

UNIVERSITY OF MICHIGAN

CONSENT TO BE PART OF A RESEARCH STUDY

INFORMATION ABOUT THIS FORM

You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.

Please take time to review this information carefully. After you have finished, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or other doctors) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. *Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.*



1. GENERAL INFORMATION ABOUT THIS STUDY AND THE RESEARCHERS

1.1 Study title: Sociobehavioral Survey Research

1.2 Company or agency sponsoring the study: Federal Granting Agency

1.3 Names, degrees, and affiliations of the researchers conducting the study:
Margaret Bell, PhD

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

On a yearly basis, we will collect information about how political and moral beliefs influence individual behavior. Examples of the topics that may be discussed include: demographic items (e.g., age, educational attainment, household income), religious and moral beliefs, current public policy issues such as gun control, taxes, Social Security and abortion, and voting and other political behavior.

3. INFORMATION ABOUT STUDY PARTICIPANTS (SUBJECTS)

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You can leave the study at any time, with no penalty to you. However, leaving the interview process early may result in your not receiving the gift certificate.

3.1 Who can take part in this study?

Any participant who is randomly selected from a telephone list may take part in this study.

3.2 How many people (subjects) are expected to take part in this study?

Approximately 300 people will participate in this study.



4. INFORMATION ABOUT STUDY PROCEDURES

4.1 What will happen to me in this study?

After receiving a phone call where a short phone interview will take place to determine your eligibility, a face-to-face interview will be scheduled to be conducted at your home. The interview will have some basic questions about you (e.g., age, educational attainment, household income), your religious and moral beliefs, thoughts about current public policy (issues including gun control, taxes, Social Security and abortion), and your voting and other political behavior.

4.2 How much of my time will be needed to take part in this study? When will my participation in the study be over?

You will be asked to participate by telephone. Once selected, you will participate in a 20 – 30 minutes face to face interview in your home.

5. INFORMATION ABOUT RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

You may feel uncomfortable answering questions that contain personal information. You may elect not to answer those questions. The research presents a slight risk of confidential information being revealed. The Researchers have procedures in place to protect participant's confidentiality. Surveys will not include participant's names; however in order to link data self-generated ID numbers will be included. Data entry will be performed by personnel separate from the primary research team. Once data is entered, self-generated ID numbers will be replaced with randomly assigned study identification numbers. The file linking study identification numbers, and the surveys, will be secured in a locked drawer and will not be made available to others. Two years after completion of the study, surveys and the linkage file will be destroyed.

5.2 If I take part in this study, can I also participate in other studies?

You may still participate in this study, even if you are participating in other studies, and the risks to you will not change. However, you should always inform all the researchers of all the studies you are participating in.

5.3 How could I benefit if I take part in this study? How could others benefit?

You will not receive any direct personal benefit from being in this study. Others may benefit from the knowledge gained from the research about relationships between individual beliefs and actions.

6. OTHER OPTIONS

6.1 If I decide not to take part in this study, what other options do I have?

It is your decision whether to participate in this study. Your only alternative option is to NOT participate in this study.



7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?


You are free to leave the study at any time. Those who choose not to continue the interview may not be entitled to the gift certificate. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please notify one of the persons listed in Section 10 “Contact Information” (below).

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

There is no harm if you leave the study before it is finished

7.3 Would the researchers take me out of the study even if I want to continue to participate?

Yes. There are reasons why the researchers may need to end your participation in the study. Some examples are:

- ✓ The researcher believes that it is not in your best interest to stay in the study.
- ✓ You become ineligible to participate.
- ✓  You do not follow instructions from the researchers.
- ✓ The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the researchers' number listed in section 10.1

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Treatment of complications
- Deductibles or co-pays for these items or services

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

By signing this form you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

You will receive a \$25.00 grocery store Gift Certificate for your participation in this study.

8.3 Who could profit or financially benefit from the study results?

- The company whose product is being studied.
- The researchers conducting the study.
- The University of Michigan


9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how your privacy and the confidentiality of your research records will be protected in this study.

9.1 How will the researchers protect my privacy?

Signing this form gives the researchers your permission to obtain, use, and share information about your survey for this study, and is required in order for you to take part in the study.

Surveys will not include names; however in order to link data from different sources self-generated ID number (you name replaced with an assigned ID number) will be included.

Data entry will be performed by personnel separate from the primary research team. The files will be secured in a locked drawer and will not be seen by members of the research team or made available to other  two years after completion of the study, surveys and files that could link you to your information will be destroyed.

9.2 What information about me could be seen by the researchers or by other people? Why? Who might see it?

There are many reasons why information about you may be used or seen by the researchers or others during this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- University and government officials may need the information to make sure that the study is done properly.
- Organizations that are funding the study may need the information to make sure that the study is done properly.
- The researchers may need to use the information to create a databank of information.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, social security number, payment amount, and related information for tax reporting purposes.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I cancel my permission?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over. Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

9.4 When does my permission expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 “Contact Information” below.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Margaret Bell, PhD

Mailing Address: 177 Medical Way, Ann Arbor 48104

Telephone: (734) 555-4233

Study Coordinator: Mary Jones, MPH

Mailing Address: 177 Medical Way, Ann Arbor 48104

Telephone: (734) 555-4121

You may also express a concern about a study by contacting the Institutional Review Board listed below, or by calling the University of Michigan Compliance Help Line at 1-888-296-2481.

University of Michigan Medical School Institutional Review Board (IRBMED)

Argus I

517 W. William

Ann Arbor, MI 48103-4943

Telephone: 734-763-4768

Fax: 734-615-1622

e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy, contact the University of Michigan Health System Privacy Officer at 1-888-296-2481.

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- ↑ This "Consent to be Part of a Research Study" document. *(Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*

12. SIGNATURES

Research Subject:

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Signature of Subject: _____ Date: _____

Name (Print legal name): _____

Patient ID: _____ Date of Birth: _____

Principal Investigator (or Designee):

I have given this research subject (or his/her legally authorized representative, if applicable) information about this study that I believe is accurate and complete. The subject has indicated that he or she understands the nature of the study and the risks and benefits of participating.

Name: _____ Title: _____

Signature: _____ Date of Signature: _____