AAPOR
AMERICAN ASSOCIATION FOR PUBLIC OPINION RESEARCH

Consent Form Examples

Here's a non-exhaustive sampling of "IRB-approved" consent documents for different forms of data collection, drawn from AAPOR members' experience and other sources. These include examples for both oral and written administration.

While all of these examples have been approved by various IRBs, please keep in mind that each IRB applies its own locally-developed standards to project review. So an example approved by one IRB might not be approved by another. However, it's AAPOR's hope that these examples will be useful in helping you meet important ethical standards and regulatory requirements when asking participants to assist us in our research.

Oral Consent

These examples require a waiver of documentation of consent (i.e., signatures) and some examples require waivers of specific elements of consent (e.g. statement of benefit or explicit statement of contact information). In most cases, contact information must be available for communication if a respondent inquires about it.

RDD Telephone Survey - Generic

Hello, my name is _____. I'm calling on behalf of [INSERT SPONSOR]. We're conducting a nationwide survey to find out [INSERT GENERAL TOPIC INFORMATION]. Your telephone number has been selected at random to be included in the study. Am I speaking to someone who lives in this household who is over 17 years old?

[RESPONDENT SELECTION – REPEAT INTRO IF NECESSARY]

Before we get to questions about [GENERAL TOPIC INFORMATION], I'd like you to know that your answers will be kept strictly private, as required by [institution/legislation/certificate of confidentiality/etc.]. Your participation in this research is voluntary. You may choose not to answer any question you don't want to answer or stop at any time without penalty. The survey will take about ___ minutes. In order to evaluate my performance, my supervisor may record and listen as I ask the questions. If you have questions about the study, I would be happy to provide a phone number for you to call to get more information. I'd like to continue now unless you have any questions.

RDD - Generic with Potential for Follow-Up

Hello, my name is _____. I'm calling on behalf of [INSERT SPONSOR]. We're conducting a nationwide survey to find out [INSERT GENERAL TOPIC INFORMATION]. Your telephone number has been selected at random to be included in the study. Am I speaking to someone who lives in this household who is over 17 years old?

[RESPONDENT SELECTION – REPEAT INTRO IF NECESSARY]

Before we get to questions about [GENERAL TOPIC INFORMATION], I'd like you to know that your answers will be kept strictly private, as required by [institution/legislation/certificate of confidentiality/etc.]. Your participation in this research is voluntary. You may choose not to answer any question you don't want to answer or stop at any time without penalty. The survey will take about ___ minutes. In some cases depending on your answers we might wish to complete a follow-up interview with you. In order to evaluate my performance, my supervisor may record and listen as I ask the questions. If you have questions about the study, I would be happy to provide a phone number for you to call to get more information. I'd like to continue now unless you have any questions.

RDD Telephone Survey of Public Policy Issues

[INTRO 1]
Hello, I'm (your name), calling from [INSERT UNIVERSITY OR ORGANIZATION] to conduct a short scientific interview. The [SPONSOR], a state committee of citizens and officials that works to improve state government, has asked us to gather input from a sample of residents on current issues of special importance to the state. Before we begin the interview...

1. Is this (telephone number)?
   1=Yes
   2=No

2. Is this a residential telephone number?
   1=Yes
   2=No

3. Your household has been chosen randomly to be included in this study. In order to determine who we need to interview from your household, I need to know how many adults, age 18 or older, live in your household.
[ ] ADULTS > IF SINGLE PERSON HOUSEHOLD SAY:

Then you are the person I need to speak with. [GO TO CONFIDENTIALITY PARAGRAPH]

4. Please tell me the age and sex of the adult who had the most recent birthday.
[ ]

5. 1=Same respondent [ALREADY SPEAKING TO SELECTED RESPONDENT, SAY:

Then you are the person I need to speak with. [GO TO CONFIDENTIALITY PARAGRAPH]

2=Someone else

6. May I speak to that person?

1=RESPONDENT COMING TO PHONE [GOTO INTRO 2]
2=NOT AVAILABLE, SCHEDULE CALLBACK

[INTRO 2]
Hello, I'm (your name), calling from [INSERT UNIVERSITY OR ORGANIZATION] to conduct a short scientific interview. The [SPONSOR], a state committee of citizens and officials that works to improve state government, has asked us to gather input from a sample of residents on current issues of special importance to the state.

[CONFIDENTIALITY PARAGRAPH - READ TO SELECTED RESPONDENT]

For most people, the interview lasts about 10 minutes, depending on how much they want to express their opinions. If this is a good time, I would like to conduct the interview with you now. Your participation is completely voluntary and confidential. We do not have your full name or address and will not ask for them. If you have questions about the study, I would be happy to provide a phone number for you to call to get more information. If I come to any question you do not wish to answer, just let me know.

RDD Telephone Survey: Cell Phone Sample

Hello, I am _____ calling on behalf of [INSERT SPONSOR/ORGANIZATION]. We are conducting a telephone opinion survey for leading newspapers and TV stations around the country. I know I am calling you on a cell phone. This is not a sales call. As a token of our appreciation for your time, we will pay all eligible respondents $5 for participating in this survey [IF R SAYS DRIVING/UNABLE TO TAKE CALL: Thank you. We will try you another time…].

SCREENING INTERVIEW:

S1. Are you under 18 years old, OR are you 18 or older?
1 Under 18
2 18 or older
9 Don't know/Refused

IF S1=2, CONTINUE WITH CONSENT
The interview is voluntary and will take about 15 minutes. There are no foreseeable risks to participation and no direct benefits to you. Your responses will be confidential and no identifying information will be stored with your answers. If you have questions about the study or your rights, I can provide contact information to you.

IF S1=1,9 THANK AND TERMINATE: This survey is limited to adults age 18 and over. I won't take any more of your time…

READ TO ALL CELL PHONE
INTRODUCTION TO MAIN INTERVIEW: If you are now driving a car or doing any activity requiring your full attention, I need to call you back later.

The first question is…

INTERVIEWER:
IF R SAYS IT IS NOT A GOOD TIME, TRY TO ARRANGE A TIME TO CALL BACK. OFFER THE TOLL-FREE CALL-IN NUMBER THEY CAN USE TO COMPLETE THE SURVEY BEFORE ENDING THE CONVERSATION.

Written Consent

Survey consent examples in this section include those with signatures and those without (which require a waiver of documentation of consent).

Generic Consent for Survey-Focus Group

Principal Investigator:
Title of Study:

You are invited to participate in this focus group/survey of _____. I am interested in finding out your views about _____
Your participation in this study will require participation in a focus group/survey and possible completion of a questionnaire. This should take approximately _____ of your time. Your participation will be confidential/anonymous and you will/will not be contacted again in the future. You will not be paid for being in this study. This focus group/survey does not involve any foreseeable risk to you and there are no direct benefits. However, the benefits of your participation may impact society by _____. You do not have to be in this study if you do not want to be. We will be happy to answer any questions you have about this study. If you have further questions about this project or if you have a research-related problem, you may contact me, _____ at _____. If you have any questions about your rights as a research participant you may contact the University of XXXXXXX Institutional Review Board (IRB) at

xxx-xxx-xxxx. An IRB is a group of people that reviews research studies to make sure that participant rights and safety are protected.

Thank you in advance for you participation in this study.

Face-to-Face Interview of Health Status

University of _____
Consent for Participation in Research
"Improving Community Health"

Why am I being asked?

You have been randomly selected from all households in _____ to participate in this community health assessment. In order to decide whether or not you want to be a part of this research study, you should understand enough about the purpose of the research project, and ask any questions you may have before agreeing to participate. You should understand the risks and benefits of participating in order to make an informed decision. This process is known as informed consent. This consent form gives detailed information the community health assessment research project, which will be discussed with you. Once you understand the study, you will be asked to sign this form if you elect to participate in the study.

What is a Community Health Assessment?
A community health assessment is a means of measuring the health status of any given community. This assessment is being funded by _____ and is being implemented by the _____. Dr. _____, from _____, have worked closely with local community organizations to design a survey instrument that is appropriate to the health needs and concerns of your community.

What is the purpose of this research?
The goal of this study is to determine what people living in six _____ community areas think about a number of health issues, and if there are certain community areas at higher-risk for certain health and medical conditions.

You are one of 1,800 people being asked to participate in this study. A professional and well-trained interviewer from the _____ will conduct a one-hour interview with you.

There are two components to this interview. The first part asks general questions that apply to you, your experiences and your health. The second part concerns the health of children under the age of 18 in your household if there are any. This second part, if your household qualifies, will be conducted with an adult who knows the most about this child (which may or may not be you).

What procedures are involved?
The first part of the interview should take approximately 45 minutes to one hour, and the second interview, if your household qualifies, should take approximately 15-20 minutes.

Will I be reimbursed for my participation in this research?
In appreciation for your time, your household will receive $40.00 for the first interview and if your household qualifies $20.00 for the second interview.

Can I withdraw or be removed from the study?
Your participation in this study is voluntary. You may choose to refuse to answer any or all questions asked of you. You also have the right to withdraw from the study at any time without penalty or any effect on your present or future relationship to _____.

What about privacy and confidentiality?
All information obtained in this study is strictly confidential. Your responses will be identified by a study code number only. Your name, or anyone else's, will NOT be used for any portion of this study. If any information is published, there will be no information that would identify you as a participant.

What are the potential risks and discomforts?
No more than minimal risk is expected during any phase of this study. Some individuals may experience discomfort when talking about various health and medical conditions; however there will no medical or health interventions offered. All information obtained from the survey will remain strictly confidential.
How do I benefit from participating in this research?
Benefits of this study will help further understand the health and medical conditions of your community area, and will help _____ to better serve your needs and direct its resources to these areas.

By signing below, you are agreeing to participate in a research study. Be sure that any of your questions about the study have been answered to your satisfaction, and that you have a thorough understanding of the research. If you have other questions or concerns about the research project, you may contact the Project Coordinator _____ or the Principal Investigator, _____. If you have any questions about your rights as a research subject or participant in this research study, you may call the Office for Protection of Research Subjects at _____.

Participant's Signature:_____
Print Name:_____
Date:_____
Interviewer's Name:_____
Date:_____

More than Minimal Risk of PTSD

Written & Recruiting & Consent Information – More than Minimal Risk Study of PTSD with Potential Follow-Up
Post-Traumatic Stress Disorder (PTSD) and Pelvic Pain
Contact Information:
If you think that you might be eligible for this study or for more information, please contact: XXXXXXXX, MD XXX-XXX-XXXX

What are some general things you should know about research studies?
Research studies are designed to gain scientific knowledge that may help other people in the future. You may not receive any direct benefit from participating. There may also be risks associated with participating in research studies.

Your participation is voluntary. You may refuse to participate, or may withdraw your consent to participate in any study at any time, and for any reason, without jeopardizing your future care at this institution or your relationship with your doctor. If you are a patient with an illness, you do not have to participate in research in order to receive treatment.

Details about this particular study are discussed below. It is important that you understand this information so that you can decide in a free and informed manner whether you want to participate. You will be given a copy of this consent form. You are urged to ask the investigators named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
The purpose of this research study is to:

1. Determine how many patients being seen in a pelvic pain clinic have experienced a trauma and have symptoms of Post-Traumatic Stress Disorder (PTSD).

2. Measure how well patients with pelvic pain are functioning in their everyday activities, and how many pain related symptoms are present.

3. Determine the effects of abuse/trauma and PTSD symptoms on pain, health related dysfunction and medical symptoms among patients with pelvic pain.

How many subjects will participate in this study?
If you decide to participate, you will be one of approximately 300 subjects in this research study.

How long will your participation last?
Your participation in this study will last for approximately thirty minutes. The entire research study will last approximately nine months.

What will happen if you take part in the study?
During the course of this study, the following will occur:

1. We will ask you to complete a survey about medical history, history of traumatic events, ability to function in daily activities, and pain and other related symptoms. The survey will also include questions about any past sexual assaults. We will also want to look at your medical record to review what treatment(s) you have received, or are currently receiving for your pelvic pain symptoms.

2. After completing the survey, you will have the option of providing your name and phone number and giving permission for further contact.

3. If you agree to further contact, you may be invited to participate in a follow-up study of pelvic pain and post-traumatic stress disorder. You would be contacted sometime within the next 9 months for further participation. Further contact would be initiated via a phone call to your home. We will take every step to completely protect your privacy. For example, in the future, if we call you at home and you answer the phone, we will identify ourselves and ask if this is a good time to talk now, or if we should attempt to reach you at a different time. If we call you at home and either an answering machine picks up, or another person answers the phone, we would simply say "We are calling from XXXX Clinics," and we would leave a name and phone number.

Are there any reasons you should not participate?
You should not participate in this study if you feel that discussing past traumatic events would be harmful to you.

What are the possible risks or discomforts?
This study might involve the following risks and/or discomforts to you:

Your answers to the initial survey may not be reviewed by your gynecologist. Only the research staff reviews the responses to the survey. The questions on the survey include topics related to a history of traumatic events, such as past sexual trauma, and other serious life events. Because this study might involve recalling past traumatic events that may cause some discomfort, it is important that you let someone know if you are feeling uncomfortable. You can tell your doctor or nurse about any discomfort, or ask to speak with a member of the research staff who is available if needed. We can immediately refer you for mental health treatment if you feel that completing the survey has caused you distress. We will take every step to protect your confidentiality. In addition, there may be uncommon or previously unrecognized risks that might occur.

What are the possible benefits?
By participating in this study, you may decide that you would like to pursue therapy for the symptoms related to PTSD or other psychiatric disorders. Please note that there are no right or wrong answers on this survey. However, if answering these survey questions causes anxiety, and/or you feel that speaking with a mental health professional would be helpful, then we encourage you to tell your doctor or nurse that you would like to be referred for treatment. With the information gained from this study, we hope to improve the detection of PTSD symptoms, so that future patients can be identified and treated more quickly.

If you choose not to participate, what other options do you have?
You do not have to participate in this research study in order to receive treatment. You can tell your doctor or nurse about any previous traumatic events and ask for more information about PTSD or the name of a doctor that can help you with cope with any serious life events that you may have experienced.

What if we learn about new risks during the study?
We do not anticipate that there will be any new risks during the study.

How will your privacy be protected?
No subjects will be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, XXXXX will take all steps allowable by law to protect the privacy of personal information.

All subjects will be given study identification numbers and no part of this research will appear in the subjects medical record. All data will be kept in a secured research area in locked file cabinets. Data management is also in a secured research area to further protect privacy.

Will you be paid for participating?
You will not be paid for participating in this research study.

Will it cost you anything to participate?
There will be no costs to you for participating.

Who is sponsoring this study?
This research is funded by the Department of XXXXXXX at XXX.

Cover Letter for Self Administered Survey

Written Consent Incorporated into Cover Letter for Self-Administered Survey – Agricultural Issues

Date

Dear (Respondent):

Farm owners and operators in this area are facing changes in a major farm program. The Conservation Reserve Program (CRP) is scheduled for re-authorization during the 2003 U.S. Senate and House hearings. Unlike the grain farms in the Midwest, grain farms in your area have unique production and land management characteristics. Information is needed to indicate how operators in this region view the CRP and how they intend to adapt to changes in the program. This information, when collected, will provide farmers, policy makers and federal farm program managers with a better local picture of how the CRP has performed and what it might become.

As an owner and/or operator with CRP acreage, I am asking your help in determining some of the characteristics concerning your operation as well as your past and future management of CRP land. We would appreciate it if you would take about 20 minutes to respond to the enclosed questionnaire and return it in the envelope provided. Your responses, together with others, will be combined and used for statistical summaries only. Your participation in this study is voluntary and you may refuse to answer any question. Only a small sample of growers will receive the questionnaire, so your participation is vital to the study.

The answers you provide will be kept confidential to the extent permitted by law. Special precautions have been established to protect the confidentiality of your responses. The number on your questionnaire will be removed once your questionnaire has been returned. We use the number to

contact those who have not returned their questionnaire, so we do not burden those who have responded. Your questionnaire will be destroyed once your responses have been tallied. There are no foreseeable risks to you as a participant in this project; nor are there any direct benefits. However, your participation is extremely valued.

If you have any questions about the survey, please contact me at (xxx) xxx-xxxx or by e-mail at xxx@xxx.edu. If I am not available when you call, please leave a message and I will call back. If you have questions about your rights as a participant in this research project, please contact the _____ Institutional Review Board (IRB) Human Protections Administrator at (xxx) xxx-xxxx or by e-mail at IRB@xxxxxxxx.edu.

Thank you for your help. We appreciate your cooperation.

Sincerely,

Name and title

Physician Practice Issues

Dear Dr. XXXXX:

We are writing to invite you to participate in an evaluation research project. The XXXX Department of Public Health is gathering information from XXXXX's citizens and primary care providers regarding Colorectal Cancer (CRC) Screening. The objective for the information gathered from the providers is to develop valid recommendations for CRC screening practices. These recommendations will eventually be made to the Centers for Disease Control and Prevention, which is funding these research projects.

Information from the providers will be gathered from surveys of 750 primary care providers and a follow-up interview of a subset of approximately 75 unique primary care practices. Of the 750 providers, 90 will be OB/GYN physicians. The survey data are being collected by the [INSERT ORGANIZATION] under the direction of [INSERT DIRECTOR]. Completion of the survey should take no more than 15 minutes. The interviews will be conducted by investigators from the [INSERT ORGANIZATION] under the direction of [INSERT DIRECTOR] and will only be completed if you explicitly provide permission for the follow-up contact to your practice. Completion of this interview should take no more than 15 minutes and may be completed by one of your designated staff members by either FAX or telephone.

Responses to the survey and interview will be confidential and no identifying information will be stored with your responses. Other than your time, the project will not involve any financial costs and no foreseeable risks beyond those encountered in your normal day-to-day activities. There is no direct benefit to participation but the information provided will be the foundation for the development of recommendations and interventions which have high likelihood of improving your ability to deliver CRC screening. As a small token of our appreciation, we are enclosing a pre-paid phone card that you may keep regardless of your decision to participate.

Your participation is voluntary. A stamped and addressed envelope has been enclosed to for your convenience. An arbitrary tracking number is affixed to facilitate survey tracking so that multiple mailings to you can be avoided. We would appreciate your returning the survey within the next 10 days. We will send a reminder card and a second mailing to those not responding initially. If you would prefer, you may complete the survey on the web at http://xx/xxxxxx using the ID XXXXX to log in. Please complete the survey using only one mode (i.e., web OR paper).

If you have any questions about the survey content, please don't hesitate to call [INSERT CONTACT] who may be reached at XXX.XXX.XXXX or by email at xxxxxx@xxxxx.edu. If you have questions about the survey administration, please contact [INSERT CONTACT] by email at xxxxx@xxxxx.edu or by phone at XXX.XXX.XXXX. If you have questions about the rights of research subjects, please contact the Human Subjects Office, XXXXXXXXXX, The University of XXXXXX, City, State, Zip, xxx.xxx.xxxx, or e-mail irb@xxxxxx.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, http://xxxxxxxx.xxxxxx.edu/hso.

Sincerely,

(Principal Investigator)

(Co-Investigator)

Student Survey of Political Issues

SURVEY INSTRUCTIONS AND CONSENT INFORMATION

Project Title: International Relations

INVITATION TO PARTICIPATE: You are being asked to participate in a research study because you are an undergraduate student enrolled in a political science course.

PURPOSE: The purpose of this survey is to assess the preferences and opinions of the class. The information will be used to shape class discussion and for research on the nature of public opinion. While the survey will not be graded in any way, please take the time to thoughtfully answer the questions.

PROCEDURES: The questionnaire should take you no more than 15 minutes to complete. Personal information (i.e., name and student identification number) is recorded in a separate location and is used to ensure students complete either the survey or the alternative assignment. When you finish the survey and see the "Thank You" screen, you will receive credit for the assignment.

RISKS: This questionnaire poses no risk to you.

BENEFITS: While this study will not benefit you directly, the resulting research should benefit society indirectly by furthering our understanding of international conflict.

ALTERNATIVES: Students declining to participate should contact the instructor for an alternative assignment.

COMPENSATION: There is no financial compensation for participating.

CONFIDENTIALITY: I understand that every attempt will be made by the investigators to maintain all information collected in this study strictly confidential, except as may be required by law. Authorized representatives of the University of XXXXXXXXX Institutional Review Board (IRB), a committee charged with protecting the rights and welfare of research subjects, may be provided access to medical or research records that identify you by name. If any publication results from this research, you will not be identified by name.

DISCLAIMER/WITHDRAWAL: I agree that my participation in this study is completely voluntary and that I may withdraw at any time without prejudicing my standing within the University or my class.

SUBJECT RIGHTS: I understand that if I wish further information regarding my rights as a research subject, I may contact [CONTACT INFORMATION] by telephoning XXX-XXX-XXXX. I also understand that if I have any questions pertaining to my participation in this research study, I may contact the principle investigator by calling the telephone number listed at the top of the page. Dr. XXXXX can also be reached by e-mail at XXXXX@XXX.edu or by traditional mail at the Department of XXXXXXX, University of XXXXXXXX, Address, City, State, Zip.

CONCLUSION: I have read and understand the consent form. I agree to participate in this research study. (Participants may print this screen for their records.)

A. I agree to participate; press START to begin.

B. I decline to participate; Close Browser to leave.

Introductory Screen Content

Conducted by the Office of

Thank you for participating in our online survey. We're conducting this survey to obtain feedback regarding your experience with . We realize that answering personal questions about this topic may be uncomfortable for you. We remind you that your participation in this project is strictly voluntary and you may refuse to participate or discontinue participation at any time during the project without penalty. You may skip any questions you don't wish to answer. If you decide to fill out the survey, all your responses will be kept strictly confidential and will only be seen by authorized members of our staff at the XXX Office of . You're welcome to contact our office at any time if you have questions about the survey. You may also contact the XXXX IRB Office (xxx.xxx.xxxx; irb@xxxxx.edu)with your questions about research participants' rights.

Data gathered from the entire project will be summarized in the aggregate, excluding references to any individual responses. The aggregated results of our analysis will be shared with departments at the

University of XXXXX and others interested in providing services to educate people about . Our office is looking for better ways to help people learn about , and to assist those who are concerned about . With your responses, we hope to identify areas that we need to improve or add to our services. Again, your input is very important to us and any information we receive from you will be kept secure and confidential.

The survey has five sections: YOUR EXPERIENCES, YOUR HABITS, WHAT DO YOU THINK, ABOUT YOU, and CONTACT INFORMATION. It will only take you about 10 minutes to complete. Once you've submitted the survey, an entry to our drawing will appear as a new page in your browser. Simply complete the form and click the Submit button to enter the drawing. Submitted entries to the drawing are stored separately from survey responses, so the two will not be linked. By entering the drawing, you will have a chance to win one of five $ STORE vouchers. Your chances of winning one of the prizes are greater than or equal to 5 in 2,000. Winners will be notified by DATE .Good luck!

Please direct any problems concerning the survey to webmaster@xxxx.edu

This informed consent statement has been approved by the University of XXXXX until MO/DA/YEAR.

You are encouraged to print a copy of this statement for your records.

[INSERT SURVEY CONTENTS HERE]