Electronic Consent Script

ELECTRONIC CONSENTING
COMMUNICATION TO PROMOTE COMPREHENSION

Study Title

We are asking you to be in a research study.
You do not have to be in the study.
If you say yes, you can quit the study at any time.
Please take as much time as you need to make your choice. Call or e-mail us if you need more information.
Your medical or observational care will not change in any way if you say no.

Why sign this document?
To be in this study, you must sign the attached consent form document.

Why are you doing this research study?
We want to learn more about how to help people who have [insert condition]. This study will help us learn more about [insert specifics]. We are asking people like you who have [insert condition] to help us.

What happens if I say yes, I want to be in the study?
If you say yes, we will:
• Ask about [describe survey items, e.g., your health, what you eat, and if you exercise, smoke, or drink alcohol, and what medicines you take].
• Give you a form on the website with questions for you to answer.
• Read the questions out loud and fill out the form with you if you want.
There is no right or wrong answer to these questions. You can skip any question you do not want to answer.

How long will the study take?
The study will take about [insert time] of your time.

What am I being asked to do?
• Briefly describe the experimental procedure and inform the participant that details of the study are fully described in the attached consent form. However, you (investigator) will be glad to explain to them in detail over the telephone or through e-mail.

What happens if I say no, I do not want to be in the study?
No one will treat you differently. You will not be penalized. [For studies with prospect of benefit, add: While you will not get the benefit of being in this study, you will not lose any

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other benefits. [For studies with no prospect of benefit, add: You will not lose any benefits.] The care you get from your doctor will not change.

What happens if I say yes, but change my mind later?
You can stop being in the study at any time. You will not be penalized. [For studies with prospect of benefit, add: While you will not get the benefit of being in this study, you will not lose any other benefits.] [For studies with no prospect of benefit, add: You will not lose any benefits.] The care you get from your doctor will not change.

Who will see my answers or my personal information?
The only people allowed to see your answers will be the people who work on the study and people who make sure we run our study the right way. [If there is a study sponsor that will have access to the data, name sponsor here.]

Your survey answers, health information, and a copy of this document will be locked in our files. We will not put your answers into your medical record.

When we share the results of the study [insert details here, e.g., in medical journals] we will not include your name. We will do our best to make sure no one outside the study will know you are a part of the study.

Will it cost me anything to be in the study?
No or describe if participants are bearing some cost.

Will being in this study help me in any way?
Being in the study will not help you, but may help people with [insert condition] in the future.

Will I be paid for my time?
Yes. We will give you [insert amount]. This is to pay you for your time. You will get this money [insert detail, e.g., at the end of the survey today] even if you decide to skip some of the questions.

Is there any way being in this study could be bad for me?
Yes. There is a chance that:
- The questions could make you sad or upset.
- Someone could find out that you were in the study and learn something about you that you did not want others to know.
- You could have a legal problem if you told us about a crime such as child abuse [list other mandatory reporting required in your state] that we have to report.

We will do our best to protect your privacy. [Insert details on additional risks if relevant to the study, such as: You could have a legal problem if someone outside the study found out that you did something illegal.]

[Insert details regarding accommodation or referrals (e.g., for counseling) if relevant to the study]

What if I have questions?
Please call the head of the study, [insert name and phone #], if you:
- Have any questions about the study.
- Have questions about your rights.
• Feel you have been injured in any way by being in this study.
You can also call the Office of Human Research at 215-255-7857 to ask questions about this study.

Do I have to sign this document?
No. You only sign this document if you want to be in the study and you will sign and mail/fax or send by e-mail the attached consent form.

What should I do if I want to be in the study?
You sign and keep a copy of the document.
By signing the document you are saying:
• You agree to be in the study.
• We talked with you about the information in this document and answered all your questions.
You know that:
• You can skip questions you do not want to answer.
• You can stop answering our questions at any time and nothing will happen to you.
• You can call the office in charge of research at [insert phone#] if you have any questions about the study or about your rights.

If study involves the use of protected health information, use the following questions to explain about how their personal information will be shared.

What information will you use and share for the study?
If you say yes, we will:
• Send this permission form to your health care providers at [insert name of institution or organization].
• Get and use [describe in detail the information to be requested and used, e.g., entire medical record, information from your record, such as how often you visited the doctor and the reason for your visits, what medicines you take, the results of lab tests, and your medical record number, sex, and date of birth].

The information we are asking to use and share is called "Protected Health Information." It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission.

If you want, we can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule you can speak to our Privacy Officer at [insert phone #].

How will you use and share this information?
• We will use your information only for the study described in this document.
• We may share your information with [list anyone outside the researchers who will receive identifiable information. For example, if there is a study sponsor that will have access to the data, name sponsor here].
• [Note to researcher: If the information is being shared for any reason other than this research study that also requires a HIPAA authorization, this purpose needs to be described. For example: We may share your name with other people doing research on [insert condition] so they can contact you about being in other research studies.]
• We will do our best to make sure your information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your information
will no longer be protected by the Privacy Rule. Let us know if you have questions about this.

• You may also request us to stop using your information at any time by sending a letter or e-mailing us and we will honor your request.