

Information taken from: Center for Health Studies

## **CLEAR WRITING TEMPLATE LANGUAGE**

### **Appendix C: Template Language for Consent Forms**

The following is a compilation of easy-to-read language for common topics in consent forms. These examples were gathered from actual language in consent forms at the Center for Health Studies (CHS), as well as consent form templates made available on the public websites of other research institutions.

CHS is still working to develop template language for HIPAA authorizations, which will be included in a future version of this toolkit.

#### Notes for users

- ! The Flesch-Kincaid formula was used to rate the approximate grade level of each selection.
- ! Feel free to combine passages from different selections or use excerpts from a specific selection in combination with other language.
- ! Phrases that will need to be revised to reflect individual research settings are highlighted in grey, with instructions for inserting specific information in brackets.

#### Topics

Table 1: Introduction/Researchers' Statement.....	pg 24
Table 2: Request for Permission to Review Medical Records.....	pg 25
Table 3: Randomization.....	pg 26
Table 4: Blood Draw Procedures.....	pg 26
Table 5: Risks of Drawing Blood.....	pg 26
Table 6: Risks of Survey Questions.....	pg 27
Table 7: No Guarantee of Direct Benefit to Participants.....	pg 27
Table 8: Voluntary Participation and Withdrawal.....	pg 28
Table 9: Confidentiality.....	pg 29
Table 10: Participant's Statement/Signature.....	pg 30
Table 11: Study Staff Statement/Signature.....	pg 31

**Table 1**

<b>Introduction/Researchers' Statement</b>	<b>Grade level</b>
<p>We are inviting you to take part in a research study. The purpose of this consent form is to give you information to help you decide if you want to be in the study. Please read this form carefully and ask study staff to explain anything you do not understand. You will have a chance to ask questions before you make your decision. This process is called 'informed consent.'</p>	<b>6.2</b>
<p>We are asking you to be in a research study. Being in this study is voluntary. To make an informed judgment on whether or not you want to be part of this study, you should understand the risks and benefits of participating. This process is known as informed consent.</p> <p>This consent form gives you detailed information about the research study. Please ask any questions you may have about the study or this form before signing it. We will give you a copy of the consent form to keep.</p>	<b>6.2</b>
<p>Please read this form carefully. Take time to ask study staff as many questions about the study as you would like. If there are any words or information that you do not understand, study staff will explain them to you. Reading this form and talking to study staff may help you decide whether to participate or not. If you decide to take part in the research study, you must sign the end of this form.</p> <p><i>from Chesapeake IRB Informed Consent Template</i></p> <p><a href="http://www.chesapeakeirb.com/us/IRBServices/Forms/tabid/83/Default.aspx">http://www.chesapeakeirb.com/us/IRBServices/Forms/tabid/83/Default.aspx</a></p>	<b>6.3</b>
<p><b>What you should know about this study:</b></p> <ul style="list-style-type: none"><li>• You are being asked to join a research study.</li><li>• This consent form explains the research study and your part in the study.</li><li>• Please read it carefully. Take as much time as you need.</li><li>• Please ask the study staff questions about anything you do not understand.</li><li>• You can ask questions now or anytime during the study.</li><li>• If you join the study, you can change your mind later.</li><li>• You can quit the study at any time.</li><li>• If you decide to quit the study, it will not affect your care at <b>Group Health</b> [insert name of facility or institution].</li></ul> <p><i>from Johns Hopkins University</i></p> <p><a href="http://irb.jhmi.edu/Forms/hipaacconsentform.rtf">http://irb.jhmi.edu/Forms/hipaacconsentform.rtf</a></p>	<b>4.8</b>

Introduction/Researchers' Statement	Grade level
<p>You are invited to think about taking part in a research study. This form will tell you about the purpose of the research, its possible risks and benefits, other options available to you, and your rights as a participant in the study. Please take your time to make your decision.</p> <p>Everyone who takes part in research at <b>Group Health [insert name of facility or institution]</b> should know that:</p> <ul style="list-style-type: none"> <li>• Being in any study is voluntary.</li> <li>• You may or may not benefit from being in the study. Knowledge we gain from this study may benefit others in the future.</li> <li>• You may leave the study at any time and none of the benefits you would normally receive would be limited or taken away.</li> <li>• Please ask any questions you have about this study. Please also take whatever time you need to talk about the study with your doctor, study staff, and your family and friends. The decision to be in the study or not is yours. If you decide to take part, please sign and date the end of this form.</li> </ul>	<b>6.7</b>

**Table 2**

Request for Permission to Review Medical Records	Grade level
<p>Checking the medical records of people in the study is an important part of this research. For this reason, we are asking that you allow us to look at your computerized records at <b>Group Health [insert name of facility or institution]</b>. We are interested in seeing what kinds of medicines you take and what kinds of visits you make in the next <b>year and a half [insert time frame]</b>.*</p>	<b>8.5</b>
<p>We will collect more information about your <b>back pain [insert condition]</b> from your computerized medical records. This will include information about medicines you have been prescribed and visits you have made to your doctor in the past <b>five years [insert time frame]</b>.*</p>	<b>10.4</b>
<p>We are asking your permission to review information in your medical records. This will include information about visits, medications, and lab tests that you have during the study.* We will use this information to compare <b>people who received extra services with people who did not receive extra services [insert applicable information]</b>.</p>	<b>10.5</b>

\* can also give a range: "...between 2000 and 2006."

**Table 3**

Randomization	Grade level
<p>We will use a computer to randomly assign you to one of the study groups. This means that you will be put into a group by chance. It is like flipping a coin or drawing names out of a hat. You will have an equal chance of being in placed in any group.</p> <p><i>adapted from an example at Georgetown University</i>  <a href="http://cra.georgetown.edu/irb/pdf/GU-Consent0805.pdf">http://cra.georgetown.edu/irb/pdf/GU-Consent0805.pdf</a></p>	3.8
<p>There will be about [500 [insert number] people in this study. They will be assigned randomly to one of three [insert number] study groups:</p> <p>[list groups]</p> <p>Which group you will be in is decided by chance, like the flip of a coin.</p>	4.8
<p>You will be randomly assigned to receive one of the four [insert number] study treatments. This means that whichever study treatment you receive will be decided purely by chance, like flipping a coin. You will have a 1 in 4 [insert odds] chance of receiving any one of the study treatments.</p> <p>We will not tell you which group you are assigned to. Study staff at your visits will not know your group assignment either. But we can quickly find out which group you are in if we ever need to know in order to protect your safety.</p>	6.7

**Table 4**

Blood Draw Procedures
<p>Note: Include volume of blood only in teaspoons or tablespoons, rather than ml, cc, or oz. Use the following equivalents:</p> <ul style="list-style-type: none"> <li>• 5cc = 1 teaspoon</li> <li>• 15cc = 1 Tablespoon</li> <li>• 1 oz = 2 Tablespoons</li> </ul>

**Table 5**

Risks of Drawing Blood	Grade level
<p>You may feel a slight needle prick when we draw your blood. Some people may have a slight bruise that will go away in a day or two. Sometimes, people feel light headed or faint.</p>	3.1

Risks of Drawing Blood	Grade level
You may feel bothered by the needle stick, and a bruise may form. In rare cases, some people faint or the site becomes infected.	4.3
There are no major risks associated with drawing blood. Having your blood drawn can be uncomfortable and can sometimes cause a bruise. In rare cases, it can cause fainting. Only trained people will draw your blood.	4.9

**Table 6**

Risks of Survey Questions	Grade level
You may feel uncomfortable answering some questions on the survey*. You may skip any question that you do not want to answer.	6.4
The interview includes some questions that may seem sensitive or personal*. You are free to skip any question or item for any reason.	7.3

\*IRBs may require that the risks section explicitly mention questions pertaining to sexual history, drug use, alcohol consumption, or other potentially sensitive topics.

**Table 7**

No Guarantee of Direct Benefit to Participants	Grade level
You may or may not receive any benefit from being in the study. It is possible that you may get better, stay the same, or get worse. If you take part in this study, other people with diabetes [insert condition] may be helped. <i>from Chesapeake IRB Informed Consent Template</i> <a href="http://www.chesapeakeirb.com/us/IRB/Services/Forms/tabid/83/Default.aspx">http://www.chesapeakeirb.com/us/IRB/Services/Forms/tabid/83/Default.aspx</a>	5.2
We do not expect you to benefit from being in this study. Others may benefit in the future from the information we get from this study.	6.7
We don't know if you will benefit from being in this study. However, we hope results of this study will help to improve treatment at Group Health [insert facility or institution] and in other health systems around the country.	7.4
We can't guarantee that you will benefit from being in this study. However, we hope to use the information from this study to develop new programs for treating back pain [insert condition].	7.9

**Table 8**

<b>Voluntary Participation and Withdrawal</b>	<b>Grade level</b>
<p><b>Can you leave the study early?</b></p> <ul style="list-style-type: none"> <li>• You can agree to be in the study now and change your mind later.</li> <li>• If you wish to stop, please tell us right away.</li> <li>• Leaving this study early will not affect your regular medical care.</li> </ul> <p><i>from Johns Hopkins University</i>  <a href="http://irb.jhmi.edu/Forms/hipaaconsentform.rtf">http://irb.jhmi.edu/Forms/hipaaconsentform.rtf</a></p>	<b>4.2</b>
<p>Being in this study is voluntary. You can decide not to be in the study. If you decide not to be in the study, you will not lose any benefits that you have.</p>	<b>4.4</b>
<p>Taking part in this study is up to you. You may choose not to take part or to leave the study at any time. If you choose not to take part or to leave the study, your regular medical care will not be affected.</p> <p><i>from Georgetown University</i>  <a href="http://ora.georgetown.edu/irb/pdf/GU-Consent0805.pdf">http://ora.georgetown.edu/irb/pdf/GU-Consent0805.pdf</a></p>	<b>4.8</b>
<p>Taking part in research is voluntary. You may decide not to be in the study. If you decide to take part, you may leave the study at any time. Your decision will not affect your medical care at <b>Group Health [insert facility or institution]</b>. There are no penalties or loss of benefits if you choose not to take part or to leave the study early.</p> <p><i>from Children's Hospital</i>  <a href="http://research.seattlechildrens.org/irs/irb/institutional-review-board.asp">http://research.seattlechildrens.org/irs/irb/institutional-review-board.asp</a></p>	<b>5.0</b>
<p>Taking part in this study is voluntary. If you choose not to participate in this study, your care at <b>Group Health [insert facility or institution]</b> will not be affected.</p> <p>You may choose not to participate at any time during the study. Leaving the study will not affect your care at <b>Group Health [insert facility or institution]</b>.</p> <p><i>from University of Chicago</i>  <a href="http://ors.bsd.uchicago.edu/IRB/InfC/ConsentFormTemplate.doc">http://ors.bsd.uchicago.edu/IRB/InfC/ConsentFormTemplate.doc</a></p>	<b>5.8</b>

<b>Voluntary Participation and Withdrawal</b>	<b>Grade level</b>
<p>Entering a research study is voluntary. Anyone who is asked to be in a research study may say no. If you start a research study, you may stop at any time. You do not need to give a reason. No doctor will treat you differently if you choose not to be in a research study or later decide to stop participating. If you stop, it is important to tell study staff and follow any instructions that they may give you.</p> <p><i>from Chesapeake IRB Informed Consent Template</i>  <a href="http://www.chesapeakeirb.com/us/IRBServices/Forms/tabid/83/Default.aspx">http://www.chesapeakeirb.com/us/IRBServices/Forms/tabid/83/Default.aspx</a></p>	<b>6.2</b>
<p>Your participation in this study is voluntary. You are free to leave this study at any time. Your care at Group Health [insert facility or institution] will not be affected by whether you decide to participate.</p>	<b>6.6</b>
<p><b>Your Rights</b></p> <p>It is important for you to know that:</p> <ul style="list-style-type: none"> <li>• Your participation is voluntary.</li> <li>• You may decide not to take part or to leave the study at any time. This will not change the quality of the health care you receive.</li> <li>• We will tell you about any new information or changes in the study that might affect your willingness to participate.</li> </ul> <p><i>from University of Massachusetts Medical School</i>  <a href="http://www.umassmed.edu/subjects/human/forms.aspx">http://www.umassmed.edu/subjects/human/forms.aspx</a></p>	<b>7.1</b>

**Table 9**

<b>Confidentiality</b>	<b>Grade level</b>
<p>Your confidentiality is one of our primary concerns. All of your research records will be kept indefinitely in locked cabinets and protected computer files. We will not place your name on any research data. Instead, we will assign a code number to your information. We will keep the master list that links your name to your code number in a locked cabinet.</p> <p>We will not share your study results with anyone unless you ask us to. Your name will not appear in any reports about this study. All information and results from this study will be kept indefinitely.</p> <p>All of the information that you give us will be confidential as provided by law. The only exception is if there is a risk of possible harm to others or to your self.</p>	<b>7.1</b>

Participant's Statement/Signature	Grade level
<p>I have read this form or have had it read to me. I have been told what will happen if I take part in this study, including the risks and benefits. I have had a chance to ask questions, and they have been answered to my satisfaction. I have been told that the people listed in this form will answer any questions I have in the future. Study staff will give me a copy of this consent form for my records. By signing below, I am voluntarily deciding to be in this research study.</p>	6.2
<p>Please initial each statement you consent to:</p> <p><input type="checkbox"/> To take part in this study.</p> <p><input type="checkbox"/> To allow the researchers to look at my <b>Group Health [insert facility or institution]</b> computerized medical records related to the health care I receive.</p> <p><input type="checkbox"/> To be contacted about this research in the future.</p>	6.8
<ul style="list-style-type: none"> <li>• This study has been explained to me.</li> <li>• I volunteer to take part in this research.</li> <li>• I have had a chance to ask questions, and my questions have been answered.</li> <li>• If I have questions later on about the research, I can ask one of the researchers listed in this form.</li> <li>• If I have questions about my rights as a research subject, I can call the <b>Group Health Human Subjects Division at (206) 287-2919 [insert applicable info]</b>.</li> <li>• I agree to allow the researchers to use my medical records as described in this consent form [remove if not applicable].</li> <li>• I understand that if I am not able to answer questions for this study in the future, study staff will contact a family member or close friend to do this for me [remove if not applicable].</li> <li>• I will receive a copy of this consent form.</li> </ul>	7.8

**Table 11**

Study Staff Statement/Signature	Grade level
<ul style="list-style-type: none"> <li>• I have carefully explained to the subject the nature and purpose of this study.</li> <li>• The subject has been given enough time and an adequate place to read and review this form.</li> <li>• The subject has had a chance to ask questions and receive answers about this study.</li> </ul> <p><i>from Chesapeake IRB</i></p> <p><a href="http://www.chesapeakeirb.com/us/IRB-Services/Forms/tabid/83/Default.aspx">http://www.chesapeakeirb.com/us/IRB-Services/Forms/tabid/83/Default.aspx</a></p>	7.3

Study Staff Statement/Signature	Grade level
I have explained the above research study <del>over the telephone</del> [remove if not applicable]. The participant was given time to discuss the study and ask questions. I can be reached at the phone number listed on this form to answer any other questions that the participant may have. I will mail [or "give," if applicable] a signed copy of the consent form to the participant.	7.5
My signature below indicates that I have fully explained this study, including its risks and benefits. I will answer any questions that you may have at any time. I also recognize that by answering study questions, you will be sharing personal information with me.	9.7

Confidentiality	Grade level
<p>We will keep information about you confidential as provided by law. We will label your audiotapes and survey answers [insert applicable study data] with a study number only. Your study number is not related to your name or Group Health medical record number [insert applicable patient identifier].</p> <p>We will keep the audiotapes in a locked cabinet. Information from the interviews will be stored in protected computer files. We will destroy the audiotapes and the link between your name and study number by March 2010 [insert date].</p> <p>We will never use your name in reports about this study. We will not share your answers with your doctor or anyone else without your permission. However, if we think you are in danger of harming yourself, we are obligated to get help for you. [use this clause only if necessary]</p>	8.0
<p>We will keep information about you confidential in accordance with the law. We will use a study number instead of your name to identify your blood sample and survey answers [insert applicable study data]. The link between your name and your ID number will be kept in a separate computer file. Access to those files will be limited to study staff with proper security clearances. You will not be identified in published reports.</p>	8.0
<p>Your privacy is important to us. We will do everything we can to protect the confidentiality of your personal information*. You will be given a study number. We will use this number on your surveys and other research papers instead of your name or Group Health consumer number [insert applicable patient identifier]. We will not include personal information about you in any reports or papers about this study.</p> <p><i>from the US Department of Justice</i>  <a href="http://www.bop.gov/newsforebp_s606.pdf">http://www.bop.gov/newsforebp_s606.pdf</a></p>	8.9

\*Note: Some IRBs may require "as provided by law" or a similar clause.

Table 10

Participant's Statement/Signature	Grade level
<ul style="list-style-type: none"> <li>• I have read this form and the research study has been explained to me.</li> <li>• I have been given the chance to ask questions, and my questions have been answered. If I have more questions, I have been told who to call.</li> <li>• I agree to be in the research study described above.</li> <li>• I will receive a copy of this consent form after I sign it.</li> </ul> <p><i>from Northwestern University</i>  <a href="http://www.research.northwestern.edu/research/OPRS/irb/informedConsent/docs/consentFormInstructions.doc">http://www.research.northwestern.edu/research/OPRS/irb/informedConsent/docs/consentFormInstructions.doc</a></p>	4.5

## Example 2

Original	Revised
<ul style="list-style-type: none"><li>• Grade level = 11.2</li><li>• Reading Ease = 51.0</li><li>• 71% passive sentences</li></ul> <p>If you meet the <b>eligibility requirements and are interested in participating</b>, you will have a 1 in 4 <b>chance</b> of being assigned to each of four groups. Three in 4 participants will be assigned to study treatment, <b>and 1 in 4</b> will be assigned to usual medical care. <b>Participants</b> assigned to the study treatment group will make 10 visits over a 7-week period. These visits will be paid for by the study. <b>All participants</b> will receive a state-of-the-art book <b>describing</b> many techniques for caring for athlete's foot. <b>Regardless of group assignment</b>, all participants will be contacted at 2, 6, and 12 months after the start of the study for about a 20-minute telephone interview. Although we cannot guarantee that you will benefit from the treatment you are <b>assigned</b>, <b>knowledge gained</b> from this study will help improve care for athlete's foot at Group Health.</p>	<ul style="list-style-type: none"><li>• Grade level = 7.1</li><li>• Reading Ease = 70.2</li><li>• 27% passive sentences</li></ul> <p>If you are <b>interested in and eligible for this study</b>, you will be assigned by chance to one of four groups. Three groups will receive study <b>treatment</b>. <b>The fourth group</b> will receive usual medical care. You will have a one in four chance of being in any group.</p> <p><b>People</b> assigned to a study treatment group will make 10 visits over a 7-week period. These visits will be paid for by the study.</p> <p><b>Everyone in the study</b> will receive a state-of-the-art book <b>about</b> different techniques for caring for athlete's foot. <b>No matter which group you are in</b>, we will call you for three telephone interviews that will last <b>about 20 minutes each</b>. <b>These interviews will take place 2, 6, and 12 months after you join the study</b>.</p> <p>We cannot guarantee that you will benefit from the treatment you may be <b>assigned</b>. <b>However</b>, we are confident that knowledge we <b>gain</b> from this study will help improve care for athlete's foot at Group Health.</p>

### Example 3

(There are revisions throughout, so changed text has not been emphasized in this example.)

Original	Revised
<ul style="list-style-type: none"><li>• Grade level = 12.0+</li><li>• Reading Ease = 44.0</li><li>• 0% passive sentences</li></ul> <p>Group Health Cooperative recognizes the importance of positive health behaviors and their role in building a healthy and rewarding lifestyle. So we want to invite you to participate in a new research study for Group Health members called the SCALP Study. Group Health Cooperative, Kaiser Permanente, and HealthMedia, Inc., a leading multimedia group, are sponsoring this research to test the effectiveness of online programs for helping people prevent and treat dandruff. Before finalizing the programs, we need to pilot test them in a small group of persons who have dandruff. If you are one of the thousands of people who say they want to do something about their dandruff, we would like to ask you to participate in this study. To be eligible to enter the study, you must have dandruff, be a member of Group Health, have an email address and the ability to access the internet at least once or twice per week, and meet certain other eligibility requirements.</p>	<ul style="list-style-type: none"><li>• Grade level = 7.7</li><li>• Reading Ease = 64.9</li><li>• 0% passive sentences</li></ul> <p>Group Health Cooperative knows that positive health behaviors play an important role in building a healthy and rewarding lifestyle. If you are one of the thousands of people who say they want to do something about their dandruff, we'd like to invite you to take part in SCALP, a new research study for Group Health members. Group Health Cooperative, Kaiser Permanente, and HealthMedia, Inc., a leading multimedia group, are sponsoring this research.</p> <p>The goal of this project is to create online programs to help people prevent and treat dandruff. To make sure that these programs are as helpful as possible, we first need to test them in a small group of people. To be eligible for the study, you must:</p> <ul style="list-style-type: none"><li>• have dandruff.</li><li>• be a member of Group Health.</li><li>• have an email address.</li><li>• be able to access the Internet at least once or twice per week.</li><li>• meet certain other eligibility requirements.</li></ul>

#### Example 4

Original	Revised
<ul style="list-style-type: none"><li>• Grade level = 11.2</li><li>• Reading Ease = 45.9</li><li>• 40% passive sentences</li></ul> <p>All of your research records will be <b>maintained indefinitely in our research offices, in locked files and password-protected</b> computer files. We will not place your name on any research data. We will assign a code number to your <b>information, and a master list identifying you by your code number will be maintained by the Principal Investigator</b> in a locked file. Only <b>investigators listed on this consent form and personnel directly related to this study</b> will have access to your study records. <b>Selected</b> people working for the study sponsors may see <b>the information about you (both personal, including your name, and other information)</b> held by the study doctor. <b>Your information will be examined</b> to confirm that it is correct and that it is related to you. These persons are required to <b>maintain the confidentiality of your information.</b> We will not reveal the results of <b>your participation to anyone unless requested by you.</b> Your name will not appear in any publications or reports <b>produced from this study.</b> All information and <b>results generated from this study</b> will be kept indefinitely.</p>	<ul style="list-style-type: none"><li>• Grade level = 7.8</li><li>• Reading Ease = 63.6</li><li>• 18% passive sentences</li></ul> <p>All of your research records will be <b>kept</b> indefinitely in <b>locked cabinets and protected</b> computer files. We will not place your name on any research data. <b>Instead, we will assign a code number to your information. We will keep the master list that links your name to your code number in a locked cabinet.</b></p> <p>Only <b>the researchers listed on this consent form and staff who work on this study</b> will have access to your study records. <b>Certain</b> people working for the study sponsors may see <b>your name or other personal information about you.</b> They will look at <b>this information</b> to confirm that it is correct. These persons are required to <b>keep your information confidential.</b></p> <p>We will not share your study results with <b>anyone unless you ask us to.</b> Your name will not appear in any reports about this study. All information and <b>results from this study</b> will be kept indefinitely.</p>

### Example 5

<p>Original</p> <ul style="list-style-type: none"><li>• Grade level = 11.4</li><li>• Reading Ease = 46.2</li><li>• 10% passive sentences</li></ul>	<p>Revised</p> <ul style="list-style-type: none"><li>• Grade level = 8.3</li><li>• Reading Ease = 63.5</li><li>• 0% passive sentences</li></ul>
<p><b>Procedures</b></p> <p>If you agree to <b>participate</b> in this study we will schedule a telephone interview at a time that is best for you. <b>The telephone call</b> will last about 30 to 60 <b>minutes</b> and will ask about your experiences with headaches and mood. <b>The interview will be audiotaped and then transcribed</b> so that we may record your responses. No one other than the research team and the transcriptionists will hear the audiotapes. We will reimburse you \$30 for your time if you <b>participate</b> in the telephone interview.</p> <p><b>In our 2002 questionnaire study</b>, you gave us information about your medical history, headaches, mood, and <b>characteristics about yourself</b>. You also gave us permission to collect information about your health care visits from your computerized medical records. For the current interview study, we would like to compare how you are feeling now with your <b>questionnaire answers and computerized records</b> from the 2002 study. We will not collect any new data about you from your medical records. By agreeing to <b>participate</b> in this study, you will be agreeing to let us compare your responses now with your responses and records from 2002.</p>	<p><b>What will happen if I join this study?</b></p> <p>If you agree to <b>be</b> in this study, we will schedule a telephone interview at a time that is best for you. <b>The call</b> will last about 30 to 60 <b>minutes</b>. <b>We</b> will ask about your experiences with headaches and mood.</p> <p><b>We will record the interview on an audiotape and then write down your answers.</b> No one other than the research team and the <b>person who writes down the answers</b> will hear the audiotapes. We will <b>give</b> you \$30 for your time if you <b>take part</b> in the telephone interview.</p> <p>For the current interview study, we would like to compare how you are feeling now with your <b>information</b> from the 2002 study. <b>In that study</b>, you gave us information about <b>yourself</b>, your medical history, your headaches, and your mood. You also gave us permission to collect information about your health care visits from your computerized medical records.</p> <p>We will not <b>look at</b> your medical records again for this study. By agreeing to <b>be</b> in this study, you are agreeing to let us compare your responses now with your responses and records from 2002.</p>