

CDC Guidance to WISEWOMAN Grantees

Consent to Participate in the Program

Requirements	State/Tribal programs must have a process in place to obtain consent from participants to participate in the WISEWOMAN Program.										
Guidance	<p>State/Tribal programs should consider combining the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) and WISEWOMAN consent forms to reduce burden on participants.</p> <p>The following table includes items that the CDC WISEWOMAN Program has determined should be included on the WISEWOMAN consent form with examples of how some of the items might be worded on the forms.</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th style="text-align: center;">Item to Include</th> <th style="text-align: center;">Examples from the Field</th> </tr> </thead> <tbody> <tr> <td>Purpose and Procedures of Program</td> <td>I agree to be in the (name of) program. This program has been designed to help women reduce their risk for heart disease, stroke, and other chronic diseases. This program provides free screening tests and a coach who will contact me to talk about easy ways to eat smart, be fit, and live well.</td> </tr> <tr> <td>List of Screening Tests</td> <td>I agree to have my height, weight, blood pressure, cholesterol, and glucose measured/tested. In addition, I understand that I will be asked some personal and family medical history and health behavior questions.</td> </tr> <tr> <td>Side Effects/Discomfort of Lab Tests</td> <td>The screening tests and possible side effects or discomfort have been explained to me.</td> </tr> <tr> <td>Return for Rescreening</td> <td>I understand that I will be asked to participate in WISEWOMAN when I return in 12-18 months for my breast and cervical annual exam appointment. The same screening tests and paperwork will be completed at that appointment. It is very important that I return for this appointment because I will learn if there are any changes in my heart disease and stroke risk and will help (name of) program learn if this program was useful.</td> </tr> </tbody> </table>	Item to Include	Examples from the Field	Purpose and Procedures of Program	I agree to be in the (name of) program. This program has been designed to help women reduce their risk for heart disease, stroke, and other chronic diseases. This program provides free screening tests and a coach who will contact me to talk about easy ways to eat smart, be fit, and live well.	List of Screening Tests	I agree to have my height, weight, blood pressure, cholesterol, and glucose measured/tested. In addition, I understand that I will be asked some personal and family medical history and health behavior questions.	Side Effects/Discomfort of Lab Tests	The screening tests and possible side effects or discomfort have been explained to me.	Return for Rescreening	I understand that I will be asked to participate in WISEWOMAN when I return in 12-18 months for my breast and cervical annual exam appointment. The same screening tests and paperwork will be completed at that appointment. It is very important that I return for this appointment because I will learn if there are any changes in my heart disease and stroke risk and will help (name of) program learn if this program was useful.
Item to Include	Examples from the Field										
Purpose and Procedures of Program	I agree to be in the (name of) program. This program has been designed to help women reduce their risk for heart disease, stroke, and other chronic diseases. This program provides free screening tests and a coach who will contact me to talk about easy ways to eat smart, be fit, and live well.										
List of Screening Tests	I agree to have my height, weight, blood pressure, cholesterol, and glucose measured/tested. In addition, I understand that I will be asked some personal and family medical history and health behavior questions.										
Side Effects/Discomfort of Lab Tests	The screening tests and possible side effects or discomfort have been explained to me.										
Return for Rescreening	I understand that I will be asked to participate in WISEWOMAN when I return in 12-18 months for my breast and cervical annual exam appointment. The same screening tests and paperwork will be completed at that appointment. It is very important that I return for this appointment because I will learn if there are any changes in my heart disease and stroke risk and will help (name of) program learn if this program was useful.										

	Item to Include	Examples from the Field
	Obligation to Refer Women with Abnormal Screening Results	The (name of) program is required to refer you to a health care provider for medical follow up if your screening values are not normal.
	Physical Activity Clearance ¹	Physical activity clearance may be needed from a health care provider before you will be referred to participate in physical activity.
	Dropping out of Program	I may drop out of this program at any time.
	Confidentiality Statement	I understand that any information about me obtained as a result of my participation in program will be kept as confidential as legally possible.
	Contact information for Questions	For more information about this program, I can contact (name and phone number of program contact).
	<p>Other information programs might want to include on the consent form includes, but is not limited to:</p> <ul style="list-style-type: none"> ▪ Eligibility Criteria ▪ Billing Responsibility ▪ A statement about sharing information with the participant’s health care provider, the state health department, and CDC <p>The consent form must be approved by CDC staff members before implementation of program direct services can occur.</p>	
Monitoring	CDC staff members will review the consent form to determine if the State/Tribal program is using a consent form that meets all CDC WISEWOMAN Program requirements.	
References	<p>¹ Programs might want to consider using the Physical Activity Readiness Questionnaire (PAR-Q) as a tool to clear women for physical activity. The tool was developed by the British Columbia Ministry of Health and an Expert Advisory Committee of the Canadian Society for Exercise Physiology revised the questionnaire in 2002. The PAR-Q can be found at http://uwfitness.uwaterloo.ca/PDF/par-q.pdf.</p>	