

Samples Alternative Procedures

Provide information on appropriate alternative procedures or courses of treatment that might be advantageous to the subject. Disclose any approved or generally recognized therapy or standard treatment that will be withheld from the subject as a result of participation in this study. Any risks to the subject in withholding the standard treatment must be disclosed in the section on Potential Risks and Discomforts.

Include a statement that significant new findings (including new alternatives to the procedures or course of treatment being offered) developed during the course of the research that may affect the subject's willingness to participate will be provided to the subject.

If this is a new treatment study, the subject must be informed of alternative procedures and courses of treatment including other investigational studies. If there is no alternative treatment, include the statement: "The alternative is not to participate." See the samples provided for suggested text on alternatives that would need to be described in the consent form. The samples may be selected for inclusion in the consent form and edited as necessary.

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Text	Sub-Heading
At this time, there are no alternative drugs for the treatment of (name of condition). The alternative to the study drug being offered is not to participate.	Medical - No Alternatives
You are eligible for this study because you have not responded to all standard therapies. One alternative is no additional intervention which could result in your disease getting worse."	Poor Response to Standard Therapy
You do not have to participate in this study to receive ongoing care for your condition.	Participation not necessary for on-going care.
This is not a study related to diagnosis or treatment of a disease or condition in eligible subjects. You are free to choose not to participate in the study.	Un-related to diagnosis
Instead of participating in this clinical trial, you may elect to receive the standard treatment for your condition, which is to receive the medicine, (name of drug). (Name of drug) reduces the frequency of cold tremors and hot flashes, the most uncomfortable symptom associated with your illness. There is no evidence to suggest that this treatment has any beneficial effect on slowing or stopping the progress of (name of condition), but it has been proven to significantly reduce the most uncomfortable symptoms of the illness in XX out of XXX patients. If you are interested in the standard treatment for (name of condition), you should discuss this option with your physician. There is also a clinical trial that you may be eligible to participate in underway at the University of XXXXX, which is testing the effectiveness of the study drug (name of drug) in treating your condition. The study, under the direction of	Medical - Other Trials

Dr. XXXXX, is sponsored by the (name of sponsor). Information on the progress of this trial is not yet available.	
Many universities around the country are currently studying the same issue. You might be able to enroll in a study at an educational institution closer to your home that would require less travel.	Alternative Site
We are not aware of any alternative study concerning this issue. The alternative is not to participate.	Non-Medical - No Alternatives