

SUGGESTED TOOL FOR ASSESSING INFORMED CONSENT

This tool was developed to help persons administering informed consent determine whether prospective participants understand the major points that must be understood before participating in a clinical trial. Ask the prospective patients the questions below and note for yourself which points were clear and which points required additional explanation. *Note: Do not record patient identifiers on this form. This form is a tool for researchers and not intended to be a study record.*

<u>Was Clear</u>	<u>Required Further Explanation</u>	
VOLUNTARY		
<input type="checkbox"/>	<input type="checkbox"/>	Do you have to participate in this research study?
<input type="checkbox"/>	<input type="checkbox"/>	Once you have signed the consent form, do you have to stay in the study until the very end?
<input type="checkbox"/>	<input type="checkbox"/>	If you decide not to enter the research study will the way your doctors and nurses treat you, change in any way?
STUDY MEDICATION		
<input type="checkbox"/>	<input type="checkbox"/>	Will you definitely receive the new drug?
<input type="checkbox"/>	<input type="checkbox"/>	What is a placebo?
BENEFITS		
<input type="checkbox"/>	<input type="checkbox"/>	Will you benefit from participating in this study?
<input type="checkbox"/>	<input type="checkbox"/>	What kind of benefits will you experience if you are assigned to the placebo group?
RISKS		
<input type="checkbox"/>	<input type="checkbox"/>	Could you be harmed by participating in this study?
<input type="checkbox"/>	<input type="checkbox"/>	Do you know who pays expenses if you need medical care or treatment due to your participation in this study?
PRIVACY/DISCLOSURE		
<input type="checkbox"/>	<input type="checkbox"/>	Will your files be kept completely private?
<input type="checkbox"/>	<input type="checkbox"/>	Do you know some of the agencies or groups who might have access to your records?
TIME REQUIRED		
<input type="checkbox"/>	<input type="checkbox"/>	How much time is required?
<input type="checkbox"/>	<input type="checkbox"/>	What will you be required to do or to have done to you for the study?
COMPENSATION		
<input type="checkbox"/>	<input type="checkbox"/>	Will you be paid for your participation in the study?
<input type="checkbox"/>	<input type="checkbox"/>	Do you know how much you receive if you do not complete the study?
<input type="checkbox"/>	<input type="checkbox"/>	Do you know when you will receive the payment?
PREGNANCY		
<input type="checkbox"/>	<input type="checkbox"/>	Is it possible for you to become pregnant or father a child during the study?
<input type="checkbox"/>	<input type="checkbox"/>	Should pregnancy or fathering a child be avoided during the study?
<input type="checkbox"/>	<input type="checkbox"/>	How can you prevent yourself from becoming pregnant or fathering a child while taking study medication?
<input type="checkbox"/>	<input type="checkbox"/>	What must you do if you become pregnant while taking the study medication?
MEDICATIONS		
<input type="checkbox"/>	<input type="checkbox"/>	Are all medications OK for you to take while you are taking the study medication?
QUESTIONS/CONTACTS		
<input type="checkbox"/>	<input type="checkbox"/>	If you have questions about the study, whom should you ask?
<input type="checkbox"/>	<input type="checkbox"/>	If you have questions about being involved in a research study, whom should you call?
<input type="checkbox"/>	<input type="checkbox"/>	Do you know whom to contact in the case of a medical emergency?
<input type="checkbox"/>	<input type="checkbox"/>	Whom should you tell about your participation in this study (health care providers)?