

CONSENT TO BE A RESEARCH SUBJECT
A Study of an Experimental Diagnostic Test

PURPOSE	A company named IVD Inc, is developing a new test to diagnose diseaseria. Diseaseria has few symptoms so getting an easy diagnostic test is important. The experimental part of the test is (...how the lab equipment analyzes the sample rather than the procedure).
PROCEDURES	If you agree to be in the study you will be a research subject. You would be agreeing to do two things. First you will have one small tube of blood drawn from an arm vein. Second, some information about your health.
RISKS / DISCOMFORTS	Drawing blood can be uncomfortable, can cause a bruise or, rarely, an infection. In order to make sure research is valid, the FDA and the company has the right to randomly audit records but not to take any identifiable information. No names or other identifiers will be recorded for this study.
BENEFITS	There will be no benefit to you. The knowledge from the study could help make a better diagnostic test.
ALTERNATIVES	The alternative to participating is refusal.
MONEY	There is no cost to you. You will be paid \$xx.xx at the end of the appointment.
QUESTIONS	If you have any questions about anything involving this study, you should ask Dr. Frankensteinl at xxx-xxx-xxxx. If you have questions about your rights or complaints you cannot take to them, you may call an impartial reviewer. Independent Review Consulting at (800) IRC-3241 or write to them at P. O. Box 170, San Anselmo, CA 94979.
RIGHTS	You have the right to refuse to participate. Once in the study, you have the right to withdraw at any time, however, you can't get the sample back since it is not identifiable. If you refuse or withdraw there will be no penalty to you.

SIGNATURES If you agree to be in this study, please sign this form,

	Subject	For a minor, a parent or guardian signs here.	Person who explained the study
Signature			
Printed name			
Date			