

# VCU INFORMED CONSENT ASSESSMENT (VCU-ICA)

Revised February 2004

Check the appropriate box to answer the following questions based on the information given to you when you signed the consent form for this research study. Your answers will remain confidential.

Question	YES	NO	UNSURE	NOT APPLICABLE	
1	Do you feel that you were informed about this research study in a way that you could understand?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	Do you need more information before continuing with this research study?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3	Were you given enough time to ask questions?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4	Did you get good answers to all of your questions?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5	Were you given a copy of the consent form to keep?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6	Are you sure you want to be part of this research study?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7	Are the words in the consent form clear to you?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8	Do you know what tests or procedures will be done on you in this research study?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9	Is it true that some of the tests, treatments or procedures done on you are not for your direct benefit but are only for research?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10	Do you know how long you will be in this research study?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Question		YES	NO	UNSURE	NOT APPLICABLE
11	Do you understand what the researchers expect you to do in this research study?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> U	<input type="checkbox"/> N A
12	Are you under any pressure to participate in this research study?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> U	<input type="checkbox"/> N A
13	Is someone available 24 hours a day to answer any questions you may have about this research study?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> U	<input type="checkbox"/> N A
14	Do you know what medical costs you or your insurance may have to pay for during this research study?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> U	<input type="checkbox"/> N A
15	Do you know what the researchers expect to learn from this research study?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> U	<input type="checkbox"/> N A
16	Can tests or procedures be done on you that are not described in the consent form?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> U	<input type="checkbox"/> N A
17	Are the medications or treatments used in this research study the only ones available for your condition?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> U	<input type="checkbox"/> N A
18	Were you promised that by participating in this research that your health will be improved?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> U	<input type="checkbox"/> N A
19	Do you know the discomforts or risks that might happen to you because of the research medicines or treatments?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> U	<input type="checkbox"/> N A
20	Do you believe that signing the consent form requires that you cannot leave the study until it is finished?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> U	<input type="checkbox"/> N A
21	Do you believe that you cannot get medical care at this hospital in the future if you do not complete this research study?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> U	<input type="checkbox"/> N A

	<b>Question</b>	<b>YES</b>	<b>NO</b>	<b>UNSURE</b>	<b>NOT APPLICABLE</b>
22	Do you give up any of your legal rights by signing the consent form?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> U	<input type="checkbox"/> N <input type="checkbox"/> A
23	Did you agree the research records from this study that identify you may be reviewed by persons or agencies other than the investigators conducting this study?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> U	<input type="checkbox"/> N <input type="checkbox"/> A
24	Do you understand that the findings in this research can be presented in meetings and published in papers?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> U	<input type="checkbox"/> N <input type="checkbox"/> A
25	Can blood or tissue taken from you during this research be used later for other research without asking you again?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> U	<input type="checkbox"/> N <input type="checkbox"/> A
26	Did you sign the consent form even though there were words in it that you did not understand?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> U	<input type="checkbox"/> N <input type="checkbox"/> A
27	Can the researchers remove you from the research study at any time?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> U	<input type="checkbox"/> N <input type="checkbox"/> A
28	Do you believe that there will be no risks or discomforts to you from the research medicines or treatments?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> U	<input type="checkbox"/> N <input type="checkbox"/> A
29	Would you volunteer to participate in this research study if there was no direct benefit to you?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> U	<input type="checkbox"/> N <input type="checkbox"/> A
30	Were you informed that only the investigator conducting this study is allowed to review the research results that identify you?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> U	<input type="checkbox"/> N <input type="checkbox"/> A
31	If you quit this research study before it is finished will you still be able to get medical care at this hospital?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> U	<input type="checkbox"/> N <input type="checkbox"/> A
32	If payment was promised for participation will you get some payment if you quit the research study early?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> U	<input type="checkbox"/> N <input type="checkbox"/> A
33	If a commercial product is developed in the future from this research study will you receive money from that?	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> U	<input type="checkbox"/> N <input type="checkbox"/> A