

# Supplement 1: Informed Consent Assessment Tool (ICAT) Template

**Informed Consent Assessment Tool (ICAT) (version of November 29, 2010)**

**Patient ID:** \_\_\_\_\_

Date enrolled in study: \_\_\_\_\_

Date ICAT administered: \_\_\_\_\_

ICAT administered face-to-face or by phone: \_\_\_\_\_

Used "current" or "new" SOP: \_\_\_\_\_

Language used to administer ICAT: \_\_\_\_\_

Interpreter used to administer ICAT: \_\_\_\_\_

Name of person administering ICAT: \_\_\_\_\_

Start Time: \_\_\_\_\_

Hello. My name is \_\_\_\_\_. I would like to ask you some questions about the discussion you had about participating in a research study. It should only take a few minutes. Your name or medical information will not appear on this form. Do you agree to answer these questions? Thank you. I will read them to you and record your answers. Please answer Yes or No. If you don't know or are not sure, just tell me you're not sure. There are no right or wrong answers. Do you have any questions before I begin? (Pause. Proceed if patient agrees.)

What language or languages do you speak well?

What language was used when you consented to participate in the research study?

1	Are you taking part in a research study?	Yes	Not Sure	No
2	Was there too much information in the papers you signed?	Yes	Not Sure	No
3	Now that you are in the study, do you have to stay in it even if you do not want to?	Yes	Not Sure	No
4	Did someone explain the study to you in words that you understood?	Yes	Not Sure	No
5	Did you have to sign the papers because your doctor gave them to you?	Yes	Not Sure	No
6	Can the study staff contact your family or friends without your approval?	Yes	Not Sure	No
7	Were there questions you wanted to ask about this study but did not ask?	Yes	Not Sure	No
8	Did you sign the papers to be part of this study without completely reading them?	Yes	Not Sure	No
9	May your private information from this study be seen by any medical person?	Yes	Not Sure	No
10	Did you have enough time to read the papers you signed to be part of this study?	Yes	Not Sure	No
11	Can you stop taking part in this study at any time?	Yes	Not Sure	No
12	Did the study staff answer your questions about this study?	Yes	Not Sure	No
13	Will you be told about any important changes in this study?	Yes	Not Sure	No
14	Can your name be used for presentations of this study?	Yes	Not Sure	No
15	Were you confused by the papers you signed for this study?	Yes	Not Sure	No
16	Does the study staff need your approval to contact your family and friends?	Yes	Not Sure	No
17	Did you need more time to read the papers you signed to be part of this study?	Yes	Not Sure	No
18	Do you know whom you can contact if you have a question about this study?	Yes	Not Sure	No
19	Can you still get care for your illness, even if you don't want to be in this study?	Yes	Not Sure	No
20	Do you have a copy of all the papers you signed?	Yes	Not Sure	No
21	Could the treatment you are receiving cause you to have side effects?	Yes	Not Sure	No
22	Must you be in the study to get medical care for tuberculosis?	Yes	Not Sure	No
23	Will this study be six to nine months long?	Yes	Not Sure	No
24	Is the treatment you are receiving in this study your only option?	Yes	Not Sure	No

**End Time:** \_\_\_\_\_

**When was the ICAT administered (please circle the correct answer below)?:**

- 1) ICAT was administered when the participant was initially enrolling in the study
- 2) ICAT was administered after the participant had already enrolled in the study

Thank you for answering these questions.