DF/HCC
DANA-FARBER / HARVARD CANCER CENTER

Office for Human Research Studies

Consent Form Reminders

March 4, 2011

1. Revised Signature Box Language: When submitting a new protocol or amendment, please make sure the highlighted language below is included in the consent form signature box for your study. The newly-added language provides information regarding the signature of an interpreter, if applicable. This language is required in all consent forms, unless the study is permanently closed to new accrual and non-English speaking subjects have never been enrolled.

To be completed by person obtaining consent:

The consent discussion was initiated on _____ (date).

A copy of this signed consent form will be given to the participant or legally authorized representative, or, where the participant is a minor, the participant's parent or legal guardian.

For Adult Participants

The participant is an adult and provided consent to participate.

Participant is a non-English speaker and signed the translated Short Form in lieu of English consent document

As someone who understands both English and the language spoken by the participant, I interpreted, in the participant's language, the researcher's presentation of the English consent form. The participant was given the opportunity to ask questions.

Signature of Interpreter: _____

Printed name of Interpreter: _____

Date: _____

The participant is an adult who lacks capacity to provide consent and his/her legally authorized representative:

gave permission for the adult participant to participate

did not give permission for the adult participant to participate

2. Risk Language Database: The DFCI IRB Common Language for Risks and Events Database provides IRB-approved language for describing risks in the consent form. This language is strongly preferred by the DFCI IRB. Use of this language will reduce the likelihood that the IRB will request changes to the risk language proposed in your consent form documents.

Note: The Common Language for Risks and Events Database can be found on our website under *Consent Documents*: http://www.dfhcc.harvard.edu/ohrs

Or it can be accessed directly at: https://oprs.dfci.harvard.edu/AE/ae_search.asp

If you have any recommended revisions to the existing language, please email Emily Eldh at: Emily_Eldh@dfci.harvard.edu

If you have any questions, please do not hesitate to contact us.

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