representatives of the Food and Drug Administration (FDA) and the National Cancer Institute (NCI) may have access to medical records which contain your identity. A qualified representative of the drug manufacturer(s) may also have access to your study records. However, no information by which you can be identified will be released or published. Histopathologic material, including slides, may be sent to a central office for review.

I have read all the above, asked questions, received answers concerning areas I did not understand and I willingly give my consent to participate in this program. Upon signing this form, I will receive a copy.

_____ (Patient signature) _____(Date)

_____ (Witness signature) _____(Date)

I, _____, willingly agree that any unused urine collected for this protocol may be stored at the Central Laboratory. This remaining urine may be used for future research that could include genetic research (about diseases that are passed on in families). This research will not have an effect on my care, therefore, neither I nor my doctor will receive results of this testing. No medical report will be added to my records. My medical records may be reviewed in the future for purposes of obtaining more information about my health, but my name and address will remain confidential and will not be released. The urine will be used for research purposes only, it will not be sold and may not have a direct benefit to me or my cancer.

If I decide now that my urine can be kept for research, I can change my mind at any time. I just need to contact my doctor and withdraw my consent for the use of my urine for research.

I have read all of the above, asked questions and received answers concerning areas that I did not understand. I willingly consent to allow my urine to be stored for future research.

_____ (Patient signature) _____(Date)

_____ (Witness signature) _____(Date)

## b. Another example of a contemporary consent form (reproduced in part)

The following reproduces, in part, a second consent form. This is the second of two consent forms that were the subject of the study of Coyne et al. (41,42,43). This second consent form contains all of the information as found in the above-reproduced consent form, plus some additional information. But the second consent form takes a more step-by-step approach suitable for understanding by the layperson:

[41] Cella D. Consent form was developed by Peter Raich for an ECOG study. E-mail of November 9, 2009.

[42] Coyne CA, Xu R, Raich P, et al. Randomized, controlled trial of an easy-to-read informed consent statement for clinical trial participation: a study of the Eastern Cooperative Oncology Group. *J Clin Oncol*. 2003;21:836–842.

[43] Permission to reproduce provided by Dr. P.C. Raich. E-mail of April 6, 2011.