DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

February 15, 2013

Dear IRB Chairs and Members,

The National Cancer Institute (NCI) has completed an initiative to revamp its Consent Form Template. The NCI has revisited the content of consent forms to address concerns of increasing length and complexity. You should notice in the coming months that the length of the consent form for new NCI-sponsored trials will have fewer pages than ones you have previously reviewed.

Studies have shown that longer consent forms are more intimidating to prospective study participants and require more time to read. The end result is that these forms are less likely to be read. The Quality of Informed Consent (QuIC) score, determined via a questionnaire measuring actual and perceived understanding of oncology trials, goes up when the consent form is 7 pages or less (Beardsley, E., et al. *JCO*, 2007, 25, e13-e14). While a consent form length of seven pages is difficult to achieve for complex oncology protocols, this work does imply that shorter is better.

All too often, the informed consent document has been viewed by sponsors as a legal tool to limit investigator and site liability rather than, as originally proposed in the Belmont Report (http://www.hhs.gov/ohrp/policy/belmont.html), part of a "process" to ensure key ethical principles for human experimentation – autonomy, beneficence, and justice – are respected (Sharp, S.M., *American Journal of Clinical Oncology*, 2004, 27(6), 570-575). There is concern that the balance has tipped in favor of comprehensiveness instead of comprehension.

This letter is being provided so IRB Chairs and Members will understand the deliberate and contemplative approach used during the extensive renovation of the NCI's Consent Form Template by experts in the field. These experts included IRB chairs, lay members, physicians, nurses, and ethicists. We have attached the revised Template to this email along with two examples of consent forms for oncology trials (phase 2 and phase 3) that indicate how the Template can be applied. Consent form authors use the Consent Form Template to draft study-specific consent forms. Of course, IRBs maintain regulatory authority to mandate changes in consent forms. However, if you have any suggestions to improve individual consent forms, we welcome your input as we view the Template as a living document that can and should evolve over time. Please address comments to: Jeanne Adler, RN, MPH, CCRP, at adlerj@mail.nih.gov

We hope you concur that on multicenter, national studies it is optimal to provide participants with a consistent consent form that doesn't deviate from one site to another. Thus, changes to the consents by local IRBs should be carefully considered. The rationale for this, on national studies, is based on the primary goal of providing uniform and consistent information to all study participants, regardless of enrolling institution.

Further, FDA and OHRP have participated fully in this Template revision and have indicated their agreement that the Template fulfills all regulatory requirements while allowing investigators to draft a shorter, more concise consent form.

While the NCI realizes that some institutional boilerplate language is required to be included in the consent form for a specific study, we ask the institution to keep in mind the necessity of reducing the length of consent forms for cancer trials and request that you use your authority to keep boilerplate language to a minimum.

Your support of more concise consent forms is appreciated and assists the NCI to better inform prospective study participants.

Sincerely,

Jeffrey Abrams, MD

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