DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

February 15, 2013

Dear Investigator:

The NCI's Consent Form Template has been revised to result in shorter, more concise consent forms for NCI-sponsored trials.

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.

The existing Template was revised by Working Groups comprised of literacy and consent form experts representing constituencies using the Template. Some of the constituencies represented were patient advocates, investigators, research nurses, IRB Chairs and members, NCI CIRB, Cooperative Group regulatory and administrative staff, and NCI staff. Changes requested by FDA and OHRP collaborators have also been incorporated in the final document. The major changes that have resulted from this review include:

- A "lay" title in addition to the official study title
- Brief description of "usual care" to place research in context
- Text examples of various trial types and phases
- Section limits
- Risks described from a study participant's perspective
- Potential side effects listed using a table format in the "Risks" section

As per the previous versions of the Template, this version complies with Federal regulations and NIH plain language principles.

The February 15, 2013 version of the NCI Consent Form Template is posted on the CTEP website at http://ctep.cancer.gov/protocolDevelopment/ and will be posted soon on the NCI's website at http://cancer.gov/clinicaltrials/understanding/simplification-of-informed-consent-docs/page3.

The dedicated efforts of the Working Group members who prepared this version of the Template are greatly appreciated. Their names are also posted on the CTEP website. Additional helpful documents posted on the CTEP website, in the "Informed Consent" section found under the "Protocol Development" tab include:

- Consent form example for a Phase 2 treatment trial, written using revised Template
- Consent form example for a Phase 3 treatment trial, written using revised Template
- Letter of rationale addressed to IRB Chairs and Members
- Instructions for building "Tables of Possible Side Effects"
- NCI Scientific Term CTCAE – IC Term Spreadsheet 12-12-12
- Repository of "Tables" for commonly-used commercials drugs
- Repository of "Tables" for commonly-used regimens (to be added within the year)

CTEP will begin using the February 15, 2013 version of the Template for review of your consent form documents as of May 15, 2013. Please utilize the February 15, 2013 version of the Template to guide preparation of consent form documents on all new protocol submissions to NCI as soon as possible.

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

Best regards,

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