NCI Informed Consent Template for Cancer Treatment Trials

Background and Action Plan

Tension exists between the requirement to provide adequate information about a cancer clinical trial in an informed consent document and the need to keep the document concise to maximize readability and comprehension. 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, 2004). There is concern that the balance has tipped in favor of comprehensiveness instead of comprehension.

Consent forms for cancer clinical trials are often lengthy and may be written at a level that is too complex for many patients to understand, particularly those who are stressed by a new diagnosis or the identification of disease progression, or who may have limited health literacy or English comprehension. The competing demands of a busy clinical setting, and the fact that many clinicians receive little training in how to conduct informed consent discussions, also hinder the informed consent process. In addition to reducing comprehensibility, a dense and lengthy consent form may also discourage a participant from joining a study, or may induce an individual to sign the informed consent document after only a cursory review without adequate understanding.

Agencies including the American Medical Association, the Agency for Healthcare Research and Quality (AHRQ), and the National Quality Forum have called for improvements in the informed consent process, and several systematic reviews summarizing the evidence for interventions to improve patient comprehension in informed consent have recently been published (Flory & Emanuel, 2004; Jefford & Moore, 2008; Schenker et al., 2010). Researchers and clinical ethicists agree it is unacceptable for trial participants to undergo study procedures and/or treatments based on oral discussion alone. Neither is it acceptable to further burden patients, already coping with the stress of a cancer diagnosis, with a complicated and lengthy document.

In 2000, the NCI developed and promulgated an informed consent boilerplate, known as the NCI Informed Consent Template, for use by the NCI's Clinical Trials Cooperative Group Program and others. This effort on NCI's part grew out of the desire to have a common approach to consent forms rather than the disparate approaches taken by organizations and individuals at the time. The aim of the NCI Informed Consent Template was to provide a prototype consent document that (i) complies with all informed consent requirements of 45 CFR 46.116 and 21 CFR 50.25; (ii) presents the informational elements common to the consent documents for most cancer clinical trials yet permits inclusion of trial-specific information; (iii) is parsimonious, has a low to moderate reading level, and presents information using plain language and other best practices drawn from the literature; and (iv) is legitimized by OHRP and the FDA.

While the informed consent template has certainly made NCI-sponsored trial consent forms more harmonious, the length of the consent forms has grown over the ensuing years to the point where there is concern now that readability and comprehension has been compromised. To address this problem, an NCI Planning Committee is taking on the challenge of revising the NCI Informed

Consent Template to achieve a more concise document that still accurately captures the required elements of informed consent. To begin this process, the Planning Committee will establish five working groups, each to be led by two non-NCI staff co-chairs and each addressing a section of the NCI Informed Consent Template, as follows:

- **Working Group 1:** Beginning of template: background, required tests, intervention sections – *Perhaps co-chaired by an external clinical investigator and an ICD author or protocol coordinator?*
- **Working Group 2:** Risks and benefits sections (also – how much standard-of-care information should be included?) – *Perhaps co-chaired by a CIRB Chair and an ICD author or regulatory specialist?*
- **Working Group 3:** Alternatives, privacy, injury, cost, rights, signature sections – *Perhaps co-chaired by an ICD expert and a protocol coordinator?*
- **Working Group 4:** Possible attachments – *Perhaps co-chaired by a patient advocate and an ICD author or protocol coordinator?*
- **Working Group 5:** Companion studies – *Perhaps co-chaired by an external translational investigator and an ICD author or protocol coordinator?*

The working groups will be comprised of internal and external stakeholders from across scientific, academic, regulatory, and advocacy communities and include representation of clinical trialists and individuals with IRB expertise. It is anticipated that three of the working groups will be tasked with addressing the text in the draft NCI Informed Consent Template in order to balance the need to provide enough information for potential trial participants to make an educated decision regarding participation, while minimizing the length and complexity of the document as much as possible. A fourth working group will be tasked with considering what attachments to append to a specific Informed Consent Document to accommodate those study participants who are interested in receiving additional, in-depth information about the study, and a fifth will consider how to address correlative studies. The working groups will be tasked with parsing out what information potential study participants require as they decide to participate in a trial, versus what additional information may be beneficial to participants once they have made the decision and are managing their participation in the clinical trial.

Once the working groups have completed their work, a face-to-face meeting of all working groups, the Planning Committee, and literacy and regulatory experts will be held to review each working group's deliverables and reach consensus on content. Additionally, a plan for promoting utilization of the NCI Informed Consent Template will be developed.

The first deliverable from the face-to-face meeting will include the NCI Informed Consent Template that meets the established aim. The second deliverable will be a guidance document targeted to IRB Chairs to accompany ICDs based on the new Template. The guidance document will outline the process followed in developing the Template, and will highlight the features of the Template that are designed to achieve maximal patient understanding and promote consent document readability and comprehension (shorter, reduced reading level; information presented in the most effective way based on best practices from the literature; etc).

The Planning Committee is also charged with determining the best way to measure the success of the informed consent forms that have been written using the NCI Informed Consent Template.

References

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