Homepage of the Month

Homepages are redesigned or modified very frequently; therefore, please note that comments in this section are based on the contents of the homepage at the time of writing.

‘Simplification of Informed Consent Documents’:
The National Cancer Institute

(http://www.cancer.gov/clinicaltrials/understanding/simplification-of-informed-consent-docs/)

The goal of the informed consent process is to provide people with sufficient information so they can make informed choices about whether to begin or continue participation in clinical research. The process involves a dynamic and continuing exchange of information between the research team and the participant throughout the research experience. It includes discussion of the study’s purpose, research procedures, risks and potential benefits, and the voluntary nature of participation. The informed consent document provides a summary of the clinical study and the individual’s rights as a research participant. The document acts as a starting point for the necessary exchange of information between the investigator and potential research participant. Also, research participants and their families may use the consent document as an information resource and reference throughout participation in the trial.

Thus, the well-written informed consent document is essential in clinical research; however, both research participants and investigators voiced concerns that informed consent documents for clinical trials were becoming too long, complicated and difficult to understand. As the response to those voices, the National Cancer Institute (NCI), along with the Office for Protection from Research Risks (now the Office of Human Research Protections) and the US Food and Drug Administration, formed an Informed Consent Working Group to propose solutions. The Working Group included a diverse group of experts: physicians, nurses, patient advocates, Institutional Review Board (IRB) members, ethicists, legal experts, communication experts and representatives of the pharmaceutical industry. In 1998, the group issued its “Recommendations for the Development of Informed Consent Documents for Cancer Clinical Trials.” The recommendations are used by investigators writing consent documents and by IRBs reviewing such documents. In addition, a consent form template was created that includes all of the federally required elements for the document, including the explanation of the research procedures, related risks and possible benefits, alternatives to participation, and the rights of research participants. This website, Simplification of Informed Consent Documents, provides the updated recommendations and templates for informed consent documents used in cancer clinical research.

The recommendations and templates provided are not only helpful for investigators when writing informed consent documents and for IRB members who review them, but also provide useful knowledge of the ethical standards for cancer clinical trials in the US. The template includes many hints for ethical controversies currently debated in Japan. For example, the model text in the template concerning compensation for health injury related to participating clinical trials is:

‘You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. The study will not pay for medical treatment.’ Additionally, it is interesting that the template includes the contact information (telephone number) of the relevant IRB for questions from participants about human rights, as IRBs in Japan commonly do not have such responsibility. The information on this site is expected to help IRB members in Japanese medical institutions to follow international ethical standards in a manner that is not unnecessarily rigorous nor too bureaucratic.

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doi:10.1093/jjco/hyh087