experts. The goal of the videotape was to encourage patient involvement by showing other patients as role models.

XIII. CONCLUDING REMARKS

Consent forms are required for clinical trials. The administrative law provides guidelines for writing consent forms. Consent forms may be written by an investigator, medical writer, or attorney, and they must be approved by an IRB or by an ethics committee.

The primary goal of consent forms, in the context of clinical trials, is to ensure that the potential subject makes an autonomous decision regarding whether to enroll in the trial. Other goals are to promote communication between the study subject and healthcare providers, promote patient enrollment, reduce drop-out rate, and reduce liability.

When new information on safety and efficacy becomes available, as the clinical trial progresses, a revised consent form may be needed (95,96). The IRB needs to review the revised consent form (97). According to Dal-Ré et al. (98), the information in a re-consent form should be new and relevant to the subject's consent. The information in the re-consent form should be relevant to the subject's willingness to continue participation in the trial. Administering re-consent forms can be appropriate when subjects are in the run-in phase, treatment phase, and even in the follow-up phase.

Regarding some fine points, consent forms also include the issues of informed consent to allow research in medical emergencies (99), informed consent for Alzheimer's disease patients (100), the problem that patients with advanced cancer have decreased comprehension, memory change, and concentration difficulty (101), allowing a surrogate to sign an informed consent for medical emergencies such as stroke (102,103), using cartoon drawings to enable children to understand their informed

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