CHAPTER 29

Consent Forms

I. INTRODUCTION

The main goal of consent forms, in the context of clinical trials, is to protect human subjects enrolled in the clinical trial. Another goal of consent forms is to protect the investigator from liability. In a study of readability of consent forms used in clinical trials, Paasche-Orlow et al. (1) stated the general proposition that, "[w]hen documents are incomprehensible, health care providers may risk liability."

Consent forms are required for regulated clinical studies, for example, those that are regulated by the FDA (2) and other regulatory agencies (3) as well as for clinical studies funded by the U.S. federal government. Federal funding for studies on human subjects includes grants from the National Institutes of Health (NIH).

The administrative law relating to consent forms reads, in part (4):

> *[N]o investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative.*

The above quotation is from Title 21 of the Code of Federal Regulations (CFR). Title 21 of the CFR is the body of administrative law that applies to the U.S. Food and Drug Administration.

a. An early clinical study using a consent form – yellow fever study

Carlos Finlay originated the theory that mosquitoes are the source of yellow fever. This theory was based on his observation that epidemics occurred coincidently with the peak in the population of the female mosquito, *Aedes aegypti*, during the hot, wet summer months. In 1881, Finlay presented his results in *The Annals of the Academy of Medical, Physical, and Natural Sciences of Havana* (5). Finlay conducted experiments with 102

[1] Paasche-Orlow MK, Taylor HA, Brancati FL. Readability standards for informed-consent forms as compared with actual readability. *New Engl J Med*. 2003;348:721–726.
[2] U.S. Department of Health and Human Services. Food and Drug Administration. Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance. April 1996.
[3] Macrae DJ. The Council for International Organizations and Medical Sciences (CIOMS) guidelines on ethics of clinical trials. *Proc Am Thorac Soc*. 2007;4:176–178.
[4] 21 Code of Federal Regulations (CFR) 50.20 (April 1, 2010 version).
[5] Tan SY, Sung H. Carlos Juan Finlay (1833–1915): of mosquitoes and yellow fever. *Singapore Med J*. 2008;49:370–371.

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