c. Summary

The consent form of the *Yellow Fever Commission* contains several vital features that are found in present-day consent forms. First, it is evident that it is a legal document, since it contains the term "contracting party." Second, it states that consent is a matter of the subject's "own very free will" and that the subject is free to leave the study ("breaks this agreement"). Third, it states the purpose of the clinical study. Fourth, it states that the clinical study is an experiment, not a treatment. Fifth, it discloses some of the risks ("endangers his life"). Sixth, it provides that the study subject will receive supportive care ("greatest care and the most skillful medical service"). The consent form used by the *Yellow Fever Commission* is an exquisite learning device for those involved in present-day clinical trials.

II. SOURCES OF THE LAW IN THE UNITED STATES

Before describing the basis of consent forms in the law, it is first necessary to outline what is the law. In short, the law includes statutes, rules, and published opinions from courtroom cases.

The sources of the law, as it applies to a great variety of human activities, include acts, the legislative history of various acts, federal and state statutes, federal administrative law, federal and state case law, and specialized sources of the law, such as the Restatement of Contracts (14) the Uniform Commercial Code (15) and various ethical doctrines. Federal statutes take the form of the United States Code (USC). Federal administrative law takes the form of the Code of Federal Regulations (CFR).

The Code of Federal Regulations consists of 50 volumes, each volume corresponding to a different arena of federal governance. For example, Title 21 is used by the FDA. Title 37 is used by the United States Patent and Trademark Office. The laws in the CFR constitute "administrative law," because they apply to various administrative agencies of the U.S. government. Administrative laws are generally not called "laws," but instead are called "rules." Administrative laws generally govern procedures, for example times for submitting paperwork, while, in contrast, statutes govern activities that are substantive in nature (16).

When new laws and administrative rules are proposed, they are published in the Federal Register. And when they are finalized, they are also published in the Federal Register. The Federal Register is a source of guidance for consent forms. Investigators and medical writers involved in drafting consent forms and re-consent forms need to

[14] Byrne JE. *Restatement 2nd of Contracts and US UCC Article 2*. 3rd ed. Montgomery Village, MD: Institute of International Banking Law & Practice; 2007;752.
[15] Uniform Commercial Code, 2009–2010 edition. Thomson West. New York, NY.
[16] Tafas v. Doll. 559 F.3d 1345; 2009 U.S. App. LEXIS 5806; 90 U.S.P.Q.2D (BNA) 1129.