Dear Readers:

Have you ever wondered if you needed Institutional Review Board approval and informed consent for a project? I am pleased to include in this issue of the Journal a paper by Dr. Ernest Prentice, Associate Dean of Research at the University of Nebraska Medical Center, on the criteria for classifying a clinical activity as research. This paper clearly and succinctly reviews federal guidelines for making this determination, and Dr. Prentice’s explanatory comments and examples make these guidelines clear and understandable. I hope you will refer to this paper when you are considering a research project so that you will be sure to adhere to the requirements mandated by the federal standards that serve to protect the rights and privacy of human subjects.

John Toomasian’s paper on minimally invasive cardiac surgery with extrathoracic cardiopulmonary bypass will be of great interest to most of you, as we begin to explore the possibilities of this new approach. This paper presents the first clinical series of 20 patients operated on with this port-access technique. Mr. Toomasian describes the technique and its benefits and pitfalls in a most understandable manner. I must admit, though, I have been a bit uncomfortable with references in the media to this technology being “consumer driven.” Hopefully, we will not abdicate our responsibility to provide proven, safe, longterm therapy for our patients with cardiac disease by succumbing to pressure for a quick, less invasive procedure. It will be our goal to define the group of patients that will benefit most from this exciting new technique.

Sincerely,

Phyllis Palmer Stark, CCP
Editor