

Safety and Effectiveness of a Biomedical Implant

Christopher Adams is just beginning his first totally independent research project as an Assistant Professor at a large biomedical research institution. This project is an outgrowth of the work he did as a postdoc. The project will examine the comparative efficacy and safety of two different types of bone implants with regard to their capacity to promote healing of fractures. The study will be carried out on dogs.

Dr. Adams has submitted a protocol review form (like the one attached) to the Institutional Animal Care and Use Committee (IACUC) and has obtained IACUC approval of the study. Previous reports in the literature indicate that both implants are nontoxic. Twenty dogs are randomly assigned to either Group 1 or Group 2 and implanted with one of the two devices. After eight weeks, the dogs will be sacrificed and the bones will be tested. At six weeks, several animals in Group 2 die. The cause of death is unknown, but the animals appear anxious and uncomfortable at the time of death. The time course of the experiment is almost up, and Dr. Adams wants to continue with the hope that at least some of the animals in Group 2 will live to eight weeks. As an alternative, he is considering sacrificing all animals at six weeks.