BACKGROUND: The higher methodological complexity of either diagnostic or therapeutic procedures has raised concern about the ethical principles that should underlie the conduct of biomedical research involving humans. AIM: To evaluate ethical problems of research proposals submitted to an ethics committee. MATERIAL AND METHODS: All research proposals involving humans, submitted within a two years period to the ethics committee of the School of Medicine of the Catholic University, were retrospectively reviewed. "Ethical problem" was defined as any explicit disagreement with the ethical principles and guidelines for the protection of human subjects involved in biomedical research, according to the Helsinki declaration. RESULTS: In 20 of 44 reviewed projects, an ethical problem was identified. The most common problems were the absence or inadequacy of the informed consent, the justification of the use of placebo and problems related to the methodological aspects of the research, particularly the lack of an adequate control group when the potential benefits of a new drug were evaluated. CONCLUSIONS: According to the Nuremberg code, the Helsinki declaration and the International Principle of Ethics in Biomedical Research, we analyse ethical problems and suggest judgement elements for them.