Abstract

For several decades Clinical trials are a “back-bone” of new drug development. Even if Ethical codices and following legislation have been actualized many times professionals are still critical to it. There is no better way than to respect valid legislation. I am interested if valid legislation that applies to informed consent of the subject participating in the clinical trial is being followed in common practice. Methodology of World Health Organization which is called Rapid Assessment and Response was applied. It has been shown by this research that deviations from the law of informed consent process are numerous. Deviations from the law of informed consent process were found in case of investigators with very rich clinical trial experience. It has been shown that errors and oversights of Investigators are not only factual nature but also ethical nature. Ethical aspects of Investigator´s errors and oversights are very often overshadowed. That is why the effort was made to detailed detection of these ethical aspects in the context of informed consent.

Due to the importance of informed consent process and on the basis of this research sponsors and regulatory authorities should ensure improvement of current situation. It is important to monitor current situation by organizing of similar research to research conducted within this dissertation.

Keywords

clinical trial, informed consent, Rapid Assessment and Response, ethics