

Ethics of research with human subjects in precision medicine

Precision medicine is also called personalized medicine and concerns a new approach in treating patients by tailoring the appropriate therapy to the individual needs and genetic characteristics of a single patient. However, before the right treatments is available, it must be evaluated during the research process with volunteers. To test new potential therapeutics in more rapid and efficient way, new models of conducting clinical trials have emerged. They are called “basket” and “umbrella” designs and they require analysis in terms of ethical standards of research involving human subjects.

Drug research in precision medicine gives hope for direct therapeutic benefit to participants. However, there is a lack of complete data on the actual benefits and risks of participating in these types of studies.

The aim of the project is to perform theoretical and ethical analyzes of basket and umbrella studies in the context of seven fundamental requirements of ethical research: 1. social or scientific value, 2. scientific validity, 3. fair subject selection, 4. favorable risk-benefit ratio, 5. independent review, 6. informed consent and 7. respect for potential and enrolled subjects.

The project is divided in three parts. The first two will focus on the risk and benefit analysis of all available basket and umbrella trials. Careful analysis of risk and benefits in novel research models in the era of precision medicine will enable the proposal of recommendations to increase the benefits for participants and society and reduce risks. The third part will be an ethical analysis based on current biomedicine standards of conducting research.

The project in innovative way combines knowledge from many disciplines, such as philosophy, ethics, bioethics and medical sciences with advanced methodological strategies. The results of the analyzes will be of great importance for bioethics, as they will be based on high-quality data and can be included in the current discussion on the ethical challenges of precision medicine. Research results will also be valuable to ethics, members of bioethics committees, researchers conducting research, sponsors and clinical trial participants worldwide.