Participants' rights, responsibilities, organisations

Index

Introduction

This article deals with the rights and potential responsibilities of research participants in the framework of clinical research, and the role of patient organisations before and during the trial.

Participants' rights

Participants of clinical trials have rights, and they are protected under law when participating in clinical trials. The informed consent process is one of the key aspects of protecting research participants. It is imperative that the decision to volunteer for a study is individual and free from undue influences that might persuade a person to consent to greater than reasonable risk. The participant has the right to know everything that is going to happen in a study. This right is accompanied by the appropriate opportunities to ask any questions and express all concerns about participation in the study. The potential participant has the right to refuse to take part in research. During the trial, the privacy of participants and the confidentiality of their data are maintained. If new benefits, risks, or side effects are discovered during a study, the researchers must inform the study participants. There are also post-trial obligations for the sponsor regarding the appropriate follow-up with study participants

Participant responsibilities

- Adherence to taking the trial medication according to the prescribed dosage and schedule. Poor medication adherence by research participants may have a detrimental effect on a trial.
- Reporting of any observation/untoward event (possible side effect) during the trial
- Participants are expected to maintain their own health and avoid unnecessary risks whilst on the trial.
- Any significant changes in participant's behavioural patterns should be discussed with the trial team as it may impact trial results (bias).

Role of patient organisations

Patient organisations can play a significant role in raising awareness about clinical trials, due to their close relationship with patients.

Dissemination, Promotion and Comprehension

Patient organisations can contribute to the dissemination of information on clinical trials and help patients to understand study aims and designs. Patient organisations involved in research activities may in some jurisdictions help to select trials for their community and advertise studies on their websites and on social networks, where the legislation permits. They may be able to mobilise resources to focus on study goal comprehension, understanding the patients' perception of benefits and risks, and take time to assess with the patients their reasons for either accepting or refusing to take part in research. Patient organisations may also identify key areas of research that they may wish to be developed and fund research. In collaboration with the research team, the patient organisation can contribute to providing written communication and accurate education tailored to the needs of the participants.

Study Adherence and Retention

The consequences of a poor adherence are important on two sides. First, the patient may be exposed to increased risk and may be harmed; and second, it can have detrimental effects on the completion of a trial itself. Patient organisations may have a positive impact in improving adherence to medications. Dissemination of trial results is critical to engage patients in the community. Communication between the study team and patients and patient organisations

will help to maintain interest and active participation in the study. The increasing use of social networks may have an influence on participation in clinical trials.

Individual Support and Protection

Patient organisations may have a role to inform and support their constituents. Patients frequently need independent advice regarding their participation or discontinuation of participation in a clinical trial. Most patient organisations will not have the resources to provide such advice themselves but may be able to suggest where patients can go to get such advice.