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Participants' Rights, Responsibilities and Role of Patient Organisations
in Clinical trials

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Participants' Rights

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- 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.

Participants' Rights

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- There should be 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.

Participants' Rights

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- 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.

Participants' Responsibilities

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- 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 patient's behavioural patterns should be discussed with the trial team as this may impact trial results possibly causing bias.

Role of Patient Organisations

Dissemination, Promotion and Comprehension

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Patient organisations (POs) can:

- play a significant role in raising awareness about clinical trials, due to their close relationship with patients;
- contribute to the dissemination of information on clinical trials and help patients to understand study aims and designs;
- identify key areas of research that they may wish to be developed and fund research;
- select trials for their community and advertise studies on their websites and on social networks;

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- take time to assess with the patients their reasons for either accepting or refusing to take part in research;
- can contribute to providing written communication and accurate education tailored to the needs of the participants in collaboration with the Research Team;
- have a positive impact in improving adherence to medications;
- be involved in the dissemination of trial results which is critical to engage patients in the community;
- suggest where patients can go to get advice about their participation or discontinuation in a clinical trial.

Study Adherence and Retention

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The consequences of poor adherence are important for two reasons:

- firstly, the patient may be exposed to increased risk and may be harmed,
- secondly, it can have detrimental effects on the completion of a trial itself.

Patient organisations can have a positive impact in improving adherence to medications.