Charter of rights and obligations of a clinical trial participant

What are the rights of a clinical trial participant?

- Participation in the clinical trial is **voluntary.**
- The decision to participate in a clinical trial must be made **consciously**.
- The patient is entitled to have sufficient time to carefully read the written information about the trial and the **informed consent form**.[1]
- The patient has the right to receive a copy of the written information about the trial and a document of informed consent signed by them and the physician for participation in the trial.
- The patient has the right to **refuse to** participate in the clinical trial. Such a decision does not involve incurring consequences, nor does it result in the loss of treatment rights.
- The patient has the right to **withdraw** their informed consent and discontinue their participation in the trial at any time and without giving any reason.
- The patient has the right to contact the principal investigator, ask questions and get them answered, and report any noticeable changes in well-being.
- At each stage of the clinical trial, the patient has the right to be informed about their health status, as well as to inspect the records.
- The patient has the right to receive information about any new data that may affect the decision regarding further participation in the clinical trial.
- The patient has the right to protection of their personal data.

> **A clinical trial shall be conducted taking into account that the rights, safety, health and well-being of the participants in the clinical trial shall prevail over the interests of science and society.**

[1] **An informed consent form** is a document on which a participant signs if they choose to take part in a clinical trial. The patient's informed consent to the participation in the clinical trial is a necessary condition for the participant to take part in any clinical trial procedure.

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Insurance and costs

In connection with participation in a clinical trial, the patient has the right to:

- seek **compensation** if they have suffered permanent damage to their health due to the use of the investigational product or the medical procedure required by the clinical trial protocol;
- obtain **reimbursement** for expenses incurred (e.g., travel or other documented costs).

The costs of the investigational product, medical care related to the trial (covered by the clinical trial protocol), specialised tests performed to qualify the participant for the study, and treatment of certain adverse reactions are covered by the **sponsor**.[2]

What is the Clinical Trials Compensation Fund?

The Compensation Fund provides financial support to a clinical trial participant who has suffered an injury as a result of participation in the trial. Applications for claims are submitted to the Patient Ombudsman and are granted for damage suffered as a result of participation in clinical trials that began after 14 April 2023.

Would you like to know more about the Clinical Trials Compensation Fund?

Detailed information can be found on the Patient Ombudsman's website:
gov.pl/web/rpp/fundusz-kompensacyjny-badan-klinicznych

[2] A **sponsor** is an individual, legal entity or unincorporated organization responsible for undertaking, conducting and financing a clinical trial,

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What are the obligations of a clinical trial participant?

- Careful review of the **informed consent form** and information for the clinical trial participant.
- Adhering to the investigator's **recommendations** and the appointment **schedule** described in the clinical trial information. If a patient plans to change or cancel a scheduled appointment, they should inform the **investigator** or the centre in advance (if possible).
- Consent to share **medical records** with the research team, sponsor representatives, inspectors/auditors, and trial results collected during the trial.
- Taking the investigational medicine **as directed by** the principal investigator and not passing it to others.
- If required, providing **empty** investigational product **packaging** and remaining unused investigational product during each subsequent appointment (not applicable if the investigational product is administered at the centre). At the request of the centre, the patient should complete the investigational product intake diary during their participation in the trial.

Did you know that...

Each participant taking part in the clinical trial, at the time of signing the informed consent, agrees to abide by the rules of participation.

It is the responsibility of the clinical trial participant to inform the investigator about:

- their current state of health;
- side effects (about any changes in health and well-being);
- medical intervention (e.g., a hospital stay or an appointment with another physician);
- newly taken medications (e.g., prescribed by a PHC physician or specialist) and supplements.

The patient should inform the physician directly providing health services who is not a member of the research team about participation in the trial.

The patient should not participate in more than one clinical trial at the same time.

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Ethical standards for conducting clinical trials

For the protection of the rights and safety of clinical trial participants and to ensure the reliability of the data obtained, national and international legal regulations and the principles of Good Clinical Practice, which are the universal standard for the implementation of clinical trials, apply.

- The **Nuremberg Code** (1947) contains 10 basic ethical principles for conducting clinical trials, stating, among other things, that informed consent for participation is a necessary condition before starting a clinical trial.
- The **Helsinki Declaration** (1964) by the World Medical Association is considered the primary document mandating adherence to certain standards of conduct with regard to the conduct of scientific research involving human subjects.
- The **Belmont Report** (1979), produced by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, is widely recognized as a key document defining principles for the implementation of scientific research involving human subjects.
- The **Good Clinical Practice** is an international document that defines the principles of designing, conducting, documenting and presenting the results of clinical trials of medicinal products. The document was developed by the International Conference on Harmonization of Good Clinical Practice (ICH GCP).

The Good Clinical Practice forms the foundation of Poland's clinical trial regulations:

- The **Act** of 9 March 2023 **on clinical trials of medicinal products for human use**, which sets forth, among other things, the rules and procedures for conducting an ethics review of a clinical trial of a medicinal product.
- The **Act** of 7 April 2022 **on medical devices**, which sets forth, among other things, the rules and procedures for conducting a clinical trial of a medical device.
- The **Act** of 5 December 1996 **on the profession of a physician and dentist**, which sets forth the rules and conditions of the profession, including the exclusive right to conduct clinical trials as an investigator.
- The **Pharmaceutical Law** of 6 September 2001, which sets forth, among other things, the rules and procedures for authorizing the marketing of medicinal products (Chapter 2).

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