Mass General Brigham
Mass Eye and Ear

Subjects participating in clinical research trials often have many questions before and during their participation. Here are some frequently asked questions (FAQs):

General Questions

1. **What is a clinical trial?**
   A clinical trial is "any investigation involving human subjects" that tests new medical treatments, drugs, or therapies to determine their safety and efficacy.

2. **Why are clinical trials important?**
   Clinical trials are crucial for developing and validating new medical approaches to enable advances in healthcare and improve existing treatments.

Eligibility & Participation

3. **Who can participate in a clinical trial?**
   Eligibility criteria may vary by study. Typically, participants are selected based on certain factors such as age, gender, medical history, and the presence of specific diseases. Each study has its own inclusion and exclusion criteria. Inclusion criteria are certain characteristics that a participant must meet to be eligible for a study. They help ensure that the study provides relevant results.

4. **Why should I participate in a clinical trial?**
   As a clinical trial participant, you will receive continuous, intensive medical care from an expert team of experienced physicians and medical staff, who are always reachable. This enables more detailed examinations than your standard medical care. Participants also gain access to new therapy options long before they were available on the market. By your willingness to participate, you will make an important contribution to the development of the therapy options of tomorrow and provide other people with an improved prospect of treatment options.

5. **What are my rights as a participant?**
   As a participant, you have the right to be fully informed about the study, including potential risks and benefits. You may terminate your participation at any time without affecting your medical care. All personal information is treated confidentially.
   Protecting the rights, safety, and welfare of people who participate in clinical trials is a critical aspect of the FDA's mission. FDA oversees clinical trials to ensure they are designed, conducted, analyzed, and reported according to federal law and **good clinical practice (GCP) regulations**. FDA's regulations and guidance for clinical trials help support efficient medical product development while assuring trials generate the robust evidence needed to assess product safety and efficacy. The agency works to ensure its GCP policies continue to facilitate new approaches to generating quality clinical evidence.

6. **Can I leave the study at any time?**
   Yes, participation is always voluntary, and you can stop it at any time without negative consequences.

7. **Will my participation affect my standard medical care?**
   Participation in clinical trials is voluntary, and your decision to participate will not affect your medical care or your relationship with the doctors and researchers.

Risks & Benefits

11. **Is it safe to participate in a clinical trial?**
    Yes, the safety of the participants is a top priority. Clinical trials are carefully planned and monitored to minimize potential risks. Before participation, researchers must disclose all risks and potential benefits of a study, and participation is always voluntary.

12. **How will I be informed of potential risks?**
    Before you choose to participate in a study, the investigator will guide you through the process. The investigator will conduct an intensive educational discussion about the course of the study with you and the potential risks and side effects of participating in the study.

    What are the possible benefits?
    It is important to understand that some risks are involved in clinical research, just as in routine medical care and activities of daily living. In thinking about the risks of research, it is helpful to focus on two things: the degree of harm that could result from taking part in the study, and the chance of any harm occurring. Most clinical studies pose risks of minor discomfort, lasting only a short time. Some volunteer subjects, however, experience complications that require medical attention. The specific risks associated with any research protocol are described in detail in the consent document, which you are asked to sign before taking part in research. In addition, the major risks of participating in a study will be explained to you by a member of the research team, who will answer your questions about the study. Before deciding to participate, you should carefully weigh these risks against possible benefits. You may or may not receive direct benefit for yourself and your condition because of participating in research, but in either case, you will know that the knowledge developed may help others.

13. **What is a study treatment or a placebo?**
    In a clinical trial, participants are often divided into two or more groups. The test group receives the treatment under investigation (e.g., a new drug), while the placebo group receives an inactive placebo or standard treatment to compare the effectiveness of the new treatment.

14. **What happens if I experience serious side effects?**
    If you experience side effects, you will need to alert the trial team so they can include those in the overall trial data. You will also need to inform your care provider and the trial team if you experience any severe side effects.

Study Procedures

16. **What will I have to do as a participant?**
    As a clinical research participant, you will typically need to provide detailed information about your medical history, undergo screening tests to confirm eligibility, follow the study protocol (which may include taking a new medication, using a medical device, or participating in specific tests), attend scheduled visits to be monitored for safety and effectiveness, and report any side effects or changes in your health to the research team

17. **How many visits are required, and where will they take place?**
    The number of visits required in a clinical trial can vary greatly depending on the study design, phase of the trial, and the type of data being collected, but typically involve multiple visits over a period of time, with some studies requiring only a single visit while others might need numerous visits for ongoing assessments and data collection; always consult the specific trial information to know how many visits are needed for a particular study.

18. **What tests, procedures, or treatments will I receive?**
    If you qualify for the clinical trial and choose to participate, you will receive the investigational treatment or intervention being studied. This may involve a new drug, medical device, procedure, behavioral intervention, or a combination of treatments. You may also undergo tests and procedures required for the study, some of which may be part of standard care for your condition.

19. **Will I need to stop taking my current medications?**
    It depends on the trial. Some trials will examine whether the treatment being tested can be used in addition to existing treatments.
    In these cases, you can continue taking your current treatments alongside the trial medication.
    Other trials will look at a new treatment meant to be used independently. You might have to stop your current therapy to participate in the trial in this scenario.
    Researchers typically do not stop people from taking their medications and switch them to placebos for four years, as this would be unfair and unethical.
    These types of trials are carefully managed and often use multi-arm, multi-stage (MAMS) designs with multiple treatment options to ensure that participants are not left on a placebo after stopping their regular treatment, which would not be ethical.

20. **How is my health monitored during the study?**
    In a clinical research study, health is monitored through a combination of regular check-ups, data collection methods like physical examinations, laboratory tests, patient-reported outcomes, and safety assessments, all conducted at the study site and often overseen by a dedicated monitoring team to ensure the study is conducted ethically and according to the protocol; this monitoring can include on-site visits, remote data review, and data safety monitoring committee (DSMC) meetings to identify any potential issues with participant health.

Costs & Compensation

21. **Will I have to pay for anything related to the study?**
    The Clinical Center does not charge patients for participation and treatment in clinical studies at NIH. In addition, in certain emergency circumstances, you may qualify for help with travel and other expenses.

22. **Will I receive compensation for my participation and travel?**
    In principle, the participation of healthy volunteers in phase I studies is remunerated. However, even in the other phases of the study, patients usually receive a Remuneration. This is dependent on various factors dependent. This includes, among other things, the possible risk and the time involved. In addition to the reimbursement of travel expenses, it is common for patients to receive lump-sum reimbursements for receiving individual visits or the entire study.

Depending on the type of study, special expenses (special examinations, more time required) will also be remunerated. Please inform yourself with the respective contact person for the study according to the exact amount of the remuneration.

23. **Does my insurance cover any standard-of-care study-related expenses?**
Under the **Patient Protection and Affordable Care Act**, new health insurance plans must cover the routine cost of care for people participating in clinical trials. However, coverage may depend on your health insurance policy, and some insurers might not cover routine tests and treatments required by the trial. This is the first federal law mandating group health plans and state-licensed health insurance issuers to cover the standard of care costs associated with participation in clinical trials.

Confidentiality & Data Use

26. **How is my personal information protected?**
All patients who participate in studies at the Clinical Center are protected by the **Patient Bill of Rights,** developed by the American Hospital Association for use in hospitals across the country. The Patients' Bill of Rights contains guidelines to ensure the privacy and confidentiality of patients and their medical records.

Patient Bill of Rights ensures that patients **receive fair and respectful treatment** in medical settings.
The Health Insurance Portability and Accountability Act (HIPPA) is a federal law that protects patients' health information and gives them rights over that information. HIPAA was passed by Congress in 1996.

HIPAA ensures that patient **health information remains private and secure**.

Feature	Patient Bill of Rights	HIPAA
Focus	Patient treatment and decision-making rights	Protection of patient health information
Legal Framework	A collection of principles; varies by law and policy	A federal law with specific regulations
Privacy Protection	Includes general privacy rights	Specifically regulates health data privacy
Right to Care	Ensures access to healthcare and informed consent	Does not regulate access to care, only information security
Scope	Covers patient-provider interactions, medical decisions, and fair treatment	Covers how medical information is handled and shared

27. **Who will have access to my data?**
In a clinical trial, access is restricted to authorized individuals to ensure confidentiality, compliance, and data integrity. Access to data is typically granted to the study sponsor (usually a pharmaceutical company or university), principal investigators at the study sites, and sometimes a data monitoring committee, with strict controls in place to protect patient privacy and access often requiring a formal data sharing agreement depending on the specific trial and regulations

involved; in some cases, qualified researchers may be able to request access to anonymized data after the trial is completed.

28. **Will my participation be shared with my doctor?**
    Participation may be shared with your doctor if:
    - You **consent** to the study team communicating with them.
    - The **study protocol** recommends or requires coordination with your doctor.
    - It is **necessary for your safety**, such as when trial treatments could affect your ongoing medical care.
    - There is a **serious health concern** (e.g., an adverse event), and informing your doctor is in your best interest.

    If you wish for your doctor to be kept informed, you can discuss this with the study team.

29. **Can I see the results of the study?**
    The data obtained will be analyzed to provide new insights and possibly further research or treatment approaches. After completion of the study, the results are usually published in scientific journals or on study websites. published. Ask your study doctor who has access to this data.

30. **How will my data be used in the future?**
    In clinical research regulations, data use is strictly governed to ensure patient privacy, data integrity, and scientific validity, requiring researchers to collect, handle, and store data responsibly, only utilizing it for the intended study purposes while adhering to informed consent guidelines and applicable privacy laws like HIPAA, typically following Good Clinical Practice (GCP) standards which emphasize accurate recording, proper documentation, and confidentiality of subject information.

For More Information:

National Institute of Health (NIH)
Are Clinical Studies for You?
FAQS-about-clinical-studies
Patient Bill of Rights
Food and Drug Administration (FDA)
Protection of Human Subjects
Good Clinical Practice
Health and Human Services (HHS)
Health Information Privacy HIPPA
Affordable Care Act ACA