What is a Principal Investigator?



What is a Clinical Trial[1]?

Clinical trials are research studies that are aimed at evaluating a medical, surgical, or behavioral intervention. They are the primary way to understand if an investigational treatment, such as a drug, diet, or medical device (such as a pacemaker) is safe and effective in people.

What is a Principal Investigator (PI)[2]?

Principal investigators are the people who oversee the clinical trial or a scientific research grant. This person is typically a doctor or other medical professional. PIs carry out the clinical trial protocols, as well as analyze the data and report the results of the trial or grant research.

General Responsibilities of a PI[3]?

1. Hire and train qualified individuals to run the trial
2. Protect patients from harm
3. Keep track of investigational treatments and distribute only as specified in the protocol
4. Obtain informed consent
5. Ensure IRB approval
6. Keep careful records and maintain them for as long as the protocol dictates or at least 2 years
7. Progress safety, financial, and final report to the study sponsors
8. Adverse events; serious adverse events must be reported immediately
9. Update financial disclosures if any circumstances change during the study
10. Strictly adhere to protocols
11. Directly supervise the study and take responsibility for study staff
12. Inform subjects of experimental nature of the drug products

Why become a PI[4]?

Some reasons becoming a PI may be important:

1. Direct contribution to the advancement of medicine
2. Gaining additional research experience and continuing medical education
3. Building a broader scientific network
4. Remain at the cutting edge of your area of interest[4]

FAQ

Who can be a PI?

Anyone who is qualified by training and experience to conduct a trial may become a PI. Experience as a physician may be preferred, but is not always required.

What type of support might the sponsor provide during the process?

The sponsor is responsible to provide any necessary training in a comprehensive way to effectively prepare and educate the PI and their staff involved in running the clinical trial. The sponsor is responsible to ensure the PI and staff fully understand the protocol and good clinical practice (GCP) requirements.

How is a relationship formed between a sponsor and a PI to conduct a clinical trial?

Generally, a clinical research agreement is entered into between a clinical trial site where the PI works or has practice rights and the sponsor. Payments made to clinical trial sites are often made for each study assessment completed for each study subject, but payment terms and conditions vary by sponsor study type.

1. https://www.nia.nih.gov/health/what-are-clinical-trials-and-studies#:~:text=Clinical%20trials%20are%20research%20studies%20that%20test%20a,a%20pacemaker%29%2C%20is%20safe%20and%20effective%20in%20people.
2. https://registries.ncats.nih.gov/glossary/principalinvestigator/
3. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7122254/
4. https://www.ppd.com/participate-in-clinical-trial/investigators/advantages-of-being-a-clinical-trial-investigator

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