PATIENT SAFETY IN CF CLINICAL TRIALS

Before enrollment

Food and Drug Administration (FDA)
FDA provides guidelines for study supervision, reviews previous studies to assess safety and approves drug to be tested in humans.

Therapeutics Development Network (TDN) Scientific Review
CF research experts from the TDN and community representatives assess the merit of the study drug, study design and safety.

Data Safety Monitoring Board (DSMB)
CF experts from the DSMB review safety data and make a plan to monitor safety during study.

Institutional Review Board (IRB)
IRB at the research site reviews the study to evaluate possible benefits and risks.

Site Study Team
Doctor at the research site reviews your health to see if you can safely participate in the study.

Patient’s Role
In the informed consent process, you are given all the available information about the study plan as well as possible risks and benefits, and your questions are answered.

During the study

Food and Drug Administration (FDA)
FDA receives ongoing notification from sponsor about the safety of the study and provides federal oversight.

Therapeutics Development Network (TDN) Study Oversight
CF researchers from the TDN rely on the DSMB to monitor the study.

Data Safety Monitoring Board (DSMB)
CF experts from the DSMB monitor all study data and take action if a safety risk is found.

Institutional Review Board (IRB)
IRB at the research site provides general oversight and monitoring during the study.

Site Study Team
Study doctor and research coordinator monitor your health during the study, and can pull you out of the study if your health is a concern.

Patient’s Role
You follow the study plan as explained during the consent process, and you keep your physician informed about how you’re feeling and any concerns you have.

For more information visit CFF.org/safety.

These safeguards are in place for all trials performed through the CFFT Therapeutics Development Network.