Government to Regulate Clinical Research Organisations

Source: LM

The government has established **Standard Operating Procedures (SOPs)** for clinical research organizations to ensure **the safety of clinical trials.** These updated regulations are part of the **New Drugs and Clinical Trials (Amendment) Rules, 2024**.

- Under this the government has defined roles, duties and liabilities to monitor through registration, approval of licence and renewal, validity period, inspection, and suspension of license if found non-compliant.
- The aim is to **maintain product quality, expedite clinical trials** of novel medications and vaccines, and bring in more transparency.
- These have been framed after consultation with **the Drugs and Technical Advisory Committee (DTAB)**.
- **Clinical Research Organization (CRO):**
  - A CRO is an entity that can be commercial, academic, individually owned, or an organization with legal status.
  - It is appointed by the sponsor to manage specific tasks, duties, or obligations.
  - These responsibilities relate to clinical trials, bioavailability, or bioequivalence studies.
  - The delegation or transfer of responsibilities must be done in writing.
- **Drugs Technical Advisory Board:**
  - It is a statutory body constituted under the **Drugs and Cosmetics Act, 1940.**
  - Its function is **to advise** the Central government and State government **on technical matters related to drugs and cosmetics.**

Read More: Drugs and Clinical Trials Rules, 2019