

Oversight of research

Health-related research involving humans

Clinical trials with drugs and medical devices

Ethics oversight

The **responsible national body** accredits **research ethics committees (RECs)**, which review and monitor research in accordance with CIOMS International ethical guidelines for health-related research involving humans.

Ethics oversight by authorities is **indirect** – through the RECs.

The relationship is between **researchers** and **RECs**.

Regulatory oversight

The **National Regulatory Authority (NRA)** oversees clinical trials with drugs, vaccines, devices and other health products in accordance with Good Clinical Practice (GCP).

Regulatory oversight by NRAs is **direct**.

The relationship is between **sponsors** and **NRAs**.

International standards for research governance

Clinical trials with drugs and medical devices

Clinical trials

Biomedical research

Health-related research involving humans

Good Clinical Practice (GCP)

International ethical guidelines (CIOMS)