

Enforcement Action Definition

Enforcement Action: Is when a problem has been discovered, usually by the FDA or some other federal agency, and an official report of the problem has been given to the study.

Examples of Enforcement actions can be:

- when there has been an unfavorable audit report;
- suspension or disqualification of an investigator;
- a FDA form 483 or Warning Letter.

The IRB needs to be made aware of these issues and the corrective actions that will be done.

For more information on Audits, please see MMC's [SOP QA 802](#).