Definitions

A Case Report Form (CRF), according to the ICH GCP guidelines, is ‘a printed, optical, or electronic document designed to record all the protocol required information to be reported to the sponsor on each trial subject.’ ICH GCP section 1.11

It is the tool for the collection of all clinical research data on each individual subject in a clinical trial.

When designing case report forms, the Data Protection Act – 1998 should be take into consideration.

SOP 38b Associated Document 1 - CRF Design Guidance

The following has been taken from SOP 38b AD 1, for more information please click here