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Clinical Study Protocol

National Cancer Institute

Source

National Cancer Institute. *Clinical Study Protocol*. NCI Thesaurus. Code C25320.

A formal document that describes a complete plan of research activity in the framework of a clinical study; specifically, the study objective(s), design, methodology, eligibility requests for prospective subjects and controls; intervention regimen(s), proposed methods of analysis of data; statistical considerations, and organization of the study. The protocol usually also provides the background and rationale for the trial, but these could be represented in other protocol referenced documents.