The IND Clinical Study Protocol

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A fully developed GCP compliant clinical protocol is the basis for both the IRB application and the initial IND application submission.

Review the IND Protocol Template for required content. A completed clinical protocol must be included in the IND application.

Start with a protocol synopsis (pages 9 to 11 of the protocol template). The protocol synopsis will be valuable if you are planning a pre-IND meeting. Compile a reference list - include all published articles and unpublished reports or manuscripts cited.

Collect a copy of each article or report listed. For approved medications, review the Prescribing Information.

Product information should be integrated into the clinical protocol. In addition, your safety plan should acknowledge known safety risks from the prescribing information and incorporate relevant safety monitoring into the clinical protocol - or show why it is not relevant to the disease under study.

Need assistance or have regulatory questions? Please contact ResearchGo.

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