In order to conduct a good research project, the study team needs a well written research protocol – a plan to carry out the project successfully. A research protocol describes the objectives, design, methodology, statistical considerations and organization of a research project. It also covers how you'll ensure the integrity of your data.

The protocol:

• Forces the writer to clarify their thoughts and think about all aspects of the study design;

• Acts as a guide for the entire study team working on the project; and,

• Is required by most IRBs or ethical committees when reviewing research.

Protocols can be created by you as the researcher – known as an Investigator-initiated protocol, or a sponsor may provide you with a protocol they designed for you to follow.

**IRB Considerations When Reviewing a Protocol**

When reviewing a protocol, the assigned IRB reviewer considers, amongst other things:

**Format of a Protocol**