

BACKGROUND

Many study designs have been presented and approved over the years. The best all had something in common: they each were well written and had internal integrity.

- ✓ The goal of the study should be clear.
- ✓ The goal should clearly fit into a larger picture.
- ✓ The objectives should contribute to the goal.
- ✓ The end points should contribute to the objectives.
- ✓ The design should allow all of the objectives to be met scientifically.
- ✓ The statistical complexity should be appropriate.

Studies are designed to answer a particular question. Some designs are adopted to gain minimum information from many subjects or, alternatively, maximum information on the fewest subjects. ***No studies are designed with ethics and subject protection as the primary goal.***

IRC REVIEW GOALS

We want subjects to be respected and protected.

We want the study to be capable of yielding evaluable results.

DOES IRC HAVE A PROTOCOL TEMPLATE OR EXAMPLES?

No. We see a broad range of protocols and what works in one discipline does not work in another. However, within this section 3.2, there is much that should be helpful.

GRANT APPLICATIONS

Grant applications make *terrible* protocols. Grants extol such virtues as the skill and background of the investigator, the importance of work in this area, a complete literature search and why funding the study is imperative. A research protocol tells HOW this can all be accomplished.

MORE INFORMATION

See the guide to protocol writing in section 3.9

