

Elements of Proposal

Title

Abstract

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Budget

CVs of Investigators

Specific aims

Background-Significance

Preliminary studies and experience of the investigators

Methods

- Overview of design
- Timeframe

Study subjects

- Selection criteria
- Design for sampling
- Plans for recruiting subjects

Measurements

- Independent variables
- Dependent variables
- Potential confounding variables

Pretest plans

Statistical Issues

- Approach to statistical analysis
- Hypothesis and sample size estimates

Quality control and data management

Timetable and organizational chart

Ethical considerations

Consultants and arrangements between institutions (multi-center study)

References

Appendices

Quality Control of Clinical Procedures

Steps that precede the study:

Develop manual of operations

Operational definitions of recruitment and measurement procedures

Standardize instruments and forms

Approach to managing and analyzing the data

Quality control systems

Train the research team

Certify the research team

Steps during the study:

Hold regular staff/team meetings

Recertify the research team

Periodically review performance

Periodically compare measurements across technicians