

Elements of a Research Protocol



1. General Information

2. Rationale & Background Information

3. Study Objectives

4. Study Design

5. Methodology

6. Safety Considerations

7. Follow-up

8. Data Management and Statistical Analysis

9. Quality Assurance

10. Expected Outcomes of the Study

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16. Budget

17. Supplementary Support for the Project

18. Collaboration With Other Researchers or Institutions

19. Curriculum Vitae of All Investigators

20. Other Research Activities of Investigators

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Writing Clinical Research Protocols

VM Jensen



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