

SPIRIT <http://www.spirit-statement.org/title/>

PROTOCOL ELEMENTS

[1-5] ADMINISTRATIVE INFORMATION

- 1: TITLE
- 2: TRIAL REGISTRATION

- 2A: REGISTRY

- 2B: DATA SET
- 3: PROTOCOL VERSION
- 4: FUNDING

- 5: ROLES AND RESPONSIBILITIES
 - 5A: CONTRIBUTORSHIP
 - 5B: SPONSOR CONTACT INFORMATION
 - 5C: SPONSOR AND FUNDER

- 5D: COMMITTEES

[6-8] INTRODUCTION

- 6: BACKGROUND AND RATIONALE

- 6A: BACKGROUND AND RATIONALE

- 6B: CHOICE OF COMPARATORS
- 7: OBJECTIVES

- 8: TRIAL DESIGN

[9-15] METHODS: PARTICIPANTS, INTERVENTIONS, OUTCOMES

- 9: STUDY SETTING
- 10: ELIGIBILITY CRITERIA

- 11: INTERVENTIONS

- 11A: INTERVENTIONS
 - 11B: MODIFICATIONS
 - 11C: ADHERENCE
-

- 11D: CONCOMITANT CARE
-

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- 12: OUTCOMES

- 13: PARTICIPANT TIMELINE

- 14: SAMPLE SIZE

- 15: RECRUITMENT

[16-17] METHODS: ASSIGNMENT OF INTERVENTIONS (FOR CONTROLLED TRIALS)

- 16: ALLOCATION

- 16A: SEQUENCE GENERATION
 - 16B: CONCEALMENT MECHANISM
-

- 16C: IMPLEMENTATION
-

- 17: BLINDING (MASKING)

- 17A: BLINDING (MASKING)
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- 17B: EMERGENCY UNBLINDING
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[18-20] METHODS: DATA COLLECTION, MANAGEMENT, ANALYSIS

- 18: DATA COLLECTION METHODS

- 18A: DATA COLLECTION METHODS
-

- 18B: RETENTION
-

- 19: DATA MANAGEMENT

- 20: STATISTICAL METHODS

- 20A: OUTCOMES

- 20B: ADDITIONAL ANALYSES
-

- 20C: ANALYSIS POPULATION AND MISSING DATA

[21-23] METHODS: MONITORING

- 21: DATA MONITORING
-

- 21A: FORMAL COMMITTEE
-

- 21B: INTERIM ANALYSIS

- 22: HARMS
-

- 23: AUDITING

[24-31] ETHICS AND DISSEMINATION

- 24: RESEARCH ETHICS APPROVAL

- 25: PROTOCOL AMENDMENTS

- 26: CONSENT OR ASSENT
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- 26A: CONSENT OR ASSENT
-

- 26B: ANCILLARY STUDIES

- 27: CONFIDENTIALITY

- 28: DECLARATION OF INTERESTS

- 29: ACCESS TO DATA

- 30: ANCILLARY AND POST-TRIAL CARE
-

- 31: DISSEMINATION POLICY

- 31A: TRIAL RESULTS

- 31B: AUTHORSHIP
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- 31C: REPRODUCIBLE RESEARCH

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- 33: BIOLOGICAL SPECIMENS