Statistics Guide for Research Grant Applicants Checklist

Tick [✓] those that apply

Design

- Is the study observational? [ ]
  (see A-1.1 and A-1.2)

  If Yes

  - Is it a cohort study? [ ]
    (see A-1.3)
  - Is it a case-control study? [ ]
    (see A-1.4)
  - Is it a cross-sectional study? [ ]
    (see A-1.5)

    If Yes to cross-sectional study

    - Is it a prevalence study? [ ]
      (see A-1.5a)
    - Is it estimating sensitivity and specificity? [ ]
      (see A-1.5b and A-1.5c)
    - Is it an ecological study? [ ]
      (see A-1.5d)
  - Have you addressed the issue of confounding in your proposal? [ ]
    (*see A-1.6)*
- Is the study experimental? [ ]
  (see A-1.1, A-1.2)

  If Yes

  - Is the study a type of trial e.g. a clinical trial? [ ]
    (see A-1.7, A-1.8)

    If Yes

    - Is the study a controlled trial
      (i.e. is there a control group)? [ ]
      (see A-1.8 and B-3)
    - Is it a randomised trial
      (i.e. are study subjects randomly allocated to groups)? [ ]
      (see A-1.8 and B-5)

      If Yes to randomised trial

      - Is it important to have similar numbers in each randomisation group? (you may need to use blocks) [ ]
        (see B-5.6)
      - Are any known factors strongly prognostic? [ ]
        (you may need to randomise in strata)
        (see B-5.7)

        If Yes to strongly prognostic factors

        - Is the proposed sample size small? [ ]
          (see B-5.8)
      - Are groups of individuals to be randomised together to the same treatment? [ ]
        (see B-5.9)
      - Is this a cross over trial? [ ]
        (see B-5.10b)
    - Is the assessor blind? [ ]
      (see A-1.8 and B-4)
    - Are the study subjects blind? [ ]
      (see A-1.8 and B-4)
- Is the study prospective? [ ]
  (see A-2)

  If Yes

  - Have you specified the length of follow up? [ ]
    (see A-2)

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The Study Subjects

(see A-3)

- Have you described where they come from? [ ]
- Have you explained why they are an appropriate group? [ ]
- Have you described how the study subjects will be selected? [ ]
- Have you specified inclusion / exclusion criteria? [ ]
- Have you specified your proposed sample size taking into account refusals/drop-outs? [ ]

Types of Variables

(see A-4)

- Have you described all outcome and explanatory variables in terms of data type and scale of measurement? [ ]
  (see A-4.1 and A-4.2)
- Have you described how the data will be collected? [ ]
  (see A-4.3)
- If using a questionnaire or a non-standard measurement, have you provided information on its reliability and validity? [ ]
  (see A-4.4, A-4.4a, A-4.4b, A-4.4c)

Sample Size

- Have you provided a sample size calculation? [ ]
  (see D-1)
- Have you defined the outcome variable(s) used in the sample size calculation? [ ]
  (see D-5)
- Have you defined the effect size which would be of clinical importance? [ ]
  (see D-4.5)
- Have you described the power and significance level of the sample size calculation? [ ]
  (see D-4.3 and D-4.4)
- Has your sample size made allowance for expected response rates and other sample attrition? [ ]
  (see D-6)
- Is your sample size consistent with the study aims? [ ]
  (see D-7)
- Is your sample size consistent with the proposed analysis of the study? [ ]
  (see D-7)
- Is your description of the sample size calculation adequate? [ ]
  (See examples in D-8)

Statistical Analysis

- Have you described the proposed statistical methods using appropriate terminology? [ ]
  (*see E-1.1, E-1.2)*
- Are the proposed methods appropriate for the *types* of data generated by your study? [ ]
  (see E-2, E-2.1, E-11)
- Will the assumptions made by the proposed methods hold? [ ]
  (see E-4, E-4.1)
- Do the proposed methods take account of the structure of the data set (structure such as hierarchy, clustering, matching, paired data)? [ ]
  (see E-3, E-6.1, E-6.2, E-10)
- Have important confounding factors been listed and methods of adjusting for them presented? [ ]
  (see E-5)
- Will the proposed methods take account of multiple testing where appropriate? [ ]
  (see E-7.1, E-7.2, E-7.3, E-7.4, E-7.4a, E-7.4b, E-7.4c, E-7.4d, E-7.4e, E-7.4f)
- Have biases due to measurement error been considered e.g. regression towards the mean? [ ]
  (*see E-8)*
- Have details on the calculation of confidence intervals been provided? [ ]
  (see E-12)

For clinical trials only

- Have you specified that your analysis will be by intention to treat? [ ]
  (see E-9)

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