

# Statistical Planning and Data Management for Grants

EPIB 707: Research Design

---

Sam Harper

McGill University

2019-10-15

The statistical analysis plan should flow from the research questions/objectives.

---

- Analysis plan should demonstrate your knowledge about:
- What data you have or you will collect:
  - Outcomes (primary, secondary, composite?).
  - Exposure / Treatment / Intervention.
  - Confounders / covariates / effect measure modifiers.
- Likely realizations of the design:
  - Classification schemes for measures.
  - Sources of error.
  - Potential for missing data.

- Analysis plan should demonstrate your knowledge about:
  - How you will analyze the resulting data.
    - Relation to study aims.
    - Model selection and justification.
    - Precision and uncertainty.
    - Sources of bias and how to mitigate.
- Statistical resources and data management:
  - Privacy, security, ethical issues.
  - Resources and expertise.
  - Transparency and reproducibility.

- Are the statistical methods adequately described?
- Is the statistical approach appropriate?
  - For the research question(s)?
  - For the study design?
  - For the type(s) of data generated?
- How credible are the statistical assumptions?
- What if they aren't?

- Use the terminology correctly and consistently
  - Multivariable, multivariate, multilevel...
  - Outcome, dependent variable, confounder, covariate, modifier, interaction...
  - Causal inference vs. descriptive aims.
- Provide additional details if a less common method is being used
  - Multiple correspondence analysis, semi Markov models, marginal structural models, etc.
- Take care with the use of the word “novel” – what is novel about it?
  - new application?
  - new method?

- Reviewer should be reassured that you have thought about how to *use* the data to meet the study objectives.
- Not:
  - “data will be analyzed using SAS”
  - “data will be analysed using multivariable methods”
- Name of the technique should be mentioned (e.g., “conditional logistic regression”), references are appropriate in statistical methods section.

## Right method for the data?

- Often there will be several analyses done depending upon the objectives.
- This can get confusing in a write up.
- Formal linkage to the specific objectives can be a useful strategy to keep things clear.
- Repeat the objective in the statistical analysis section.



# Structure of the analysis section tied to aims

## 1. Separate methods for each aim:

- *Specific Aim #1*
  - Data analysis plan
- *Specific Aim #2*
  - Data analysis plan
- *Specific Aim #3*
  - Data analysis plan

## 2. Overarching methods for all aims:

- *Specific Aim #1, #2, #3*
  - Data analysis plan.