Key Elements of a Research Protocol

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HRB aims to fund ……

- Researchers and Research Teams………

- …new knowledge

- …evidence of benefit to health, through
  - patient-oriented research
  - population health sciences research
  - health services research

- Focus is similar for Health Research Awards and Training Fellowships
Research Protocol - I

What is a Research Protocol?

- A formal document specifying what the study hopes to achieve and how it is to be conducted

When should you write a Research Protocol?

- For every research project, no matter how small or seemingly insignificant

- Before doing anything else!
Why should you write a Research Protocol?

- to organise your thinking
- to clarify the question(s) being asked
- to facilitate discussion with colleagues
- to reduce the risk of digressions during project

- to compete for funding
- for submission to Research Ethics Committee
- to submit your MSc / PhD proposal & get it accepted!
- to ensure continuity of the project if necessary
How should you write a Research Protocol?

- Know the Key Elements of a Research Protocol
- Engage with a Multidisciplinary Team
- Give yourself adequate time!
  - Deadlines within deadlines, e.g. Institutional requirements
- Be prepared to draft and redraft!
The Research Team ....

- Breadth & depth of expertise in scientific / clinical / methodological areas
- Expertise in statistics, health economics, HSR, behavioural sciences, qualitative research, sociology, trialists (for RCTs)
- Add as Co-applicants / Collaborators
- Partner Organisations, e.g. academic, health service providers, government, charities

Adds to **Complexity**, but synergistic for **Quality**
Key Elements of a Research Protocol
The Research Question

- ‘Research’ usually begins with a **general** question of interest to you, which may arise from
  - an observation within your area of work or interest
  - a prompt or issue in your field of study
  - prior research of relevance

- However, usually **too general**!

- Needs to be formulated into a **specific** question that can be investigated

- Once question defined, a systematic approach to the investigation must follow (research)
Current Knowledge / Background

- **Size / nature of issue**
  - State the issue!
  - Identify & summarise previous knowledge / work through comprehensive literature review, searches for relevant national data, pilot work, etc
  - Seek collaboration / multidisciplinary input

- **Relevance / Importance**
  - Identify the potential contribution / significance of your work to existing body of knowledge
Literature Review: Mechanics

- Literature Searches: Which Databases?
- Keywords / Terms: MeSH Databases / PubMed
- Type of Publication: Original Research Papers
- Type of Publication: Reviews
- Type of Publication: Meta analyses
- Type of Publication: Editorials / Letters

- Time Period: Recent
- Time Period: Do not ignore KEY old papers

- Citation Alerts: Sign Up

- Referencing System: EndNote / Reference Manager
Literature Review: Content

- Review published works to date on this question
- Identify gaps in current knowledge / What can your research contribute?
  - e.g. Is there a literature specific to Ireland on this topic?
- Be critical of published literature and of your proposal
- Avoid the need to find a literature to support your preconceived ideas / what you have already done!
- Include relevant literature only!
- Beware of plagiarism! Review policies on plagiarism, e.g. [http://www.ucd.ie/library/students/information_skills/plagiari.html](http://www.ucd.ie/library/students/information_skills/plagiari.html)
Specific Aims / Objectives

Statement of the Question(s) to be answered
Statement of the Hypothesis(es) to be tested

Structure of the Statement of Objectives:
- To describe …
- To examine …
- To determine …
- To analyse …

Structure of Statements of Hypotheses:
- Null hypothesis (Ho): There is no difference
- Alternative hypothesis (Ha): There is a difference
Study Design / Methods

**OBSERVATIONAL**

- Descriptive
  - Retrospective
  - Cross-sectional
  - Prospective

- Analytical
  - Case-control
  - Association
  - Cohort

**EXPERIMENTAL**

- Analytical
  - Clinical trials
  - Intervention trials
Sources of Participants / Data

- Population-based
- Clinic attendees
- Hospital inpatients
- Selected subgroups
  - Specific disease subgroups (DM, HIV…)
  - Specific exposures
  - Patients with known familial or genetic characteristics
- Survey / Questionnaire
- Interview data
- Focus Groups
- Medical record review
- Employment records
- Registry data
- Vital statistics
Eligibility Criteria (Incl / Excl)

**DEMOGRAPHIC**
- Age, Gender
- Occupational
- Ethnic Group
- Geographic Area

**BIOLOGICAL**
- Specific parameters
- Specified ranges

**DIAGNOSTIC**
- Decide on criteria prior to recruitment / inclusion
- Use standard criteria where possible
- Define cut off points
- Establish hierarchy of sources of diagnostic data
Objective of Sampling

- To reduce cost and workload
  - while
- Maintaining representativeness and relevance for extrapolation of results to the larger population of interest

- Know your **Sampling Frame** (size, location, characteristics, availability, accessibility)
Sampling Methods

**Epidemiologic Sampling**
- Simple random sampling
- Systematic sampling
- Stratified sampling
- Cluster sampling
- Stratified Cluster Sampling

**Convenience Sampling**
- Caveats!!
Sample Size Estimation

- For almost every type of study
- Different inputs depending on study design
- Well laid out in statistical texts
- Trade off between power and practicality
- Be prepared to abandon study if necessary
- Get help!
# Objective of Sample Size Estimation

<table>
<thead>
<tr>
<th>Type</th>
<th>Objective</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Descriptive</strong></td>
<td>Adequate sample size to ensure desired precision of a single estimate / mean or proportion (prevalence)</td>
</tr>
<tr>
<td><strong>Analytical</strong></td>
<td>Adequate sample size to ensure statistical significance of difference in risk</td>
</tr>
<tr>
<td><strong>RCT</strong></td>
<td>Adequate sample size to ensure statistical significance of estimate of change / benefit</td>
</tr>
<tr>
<td><strong>Community Intervention</strong></td>
<td>Sample size to estimate NNT / benefit to community at large</td>
</tr>
</tbody>
</table>
Recruitment Issues

- Know your “pool” (Incidence / prevalence data)
- Feasibility / Organisation of recruitment
- Duration / How long do you have?
- Participant information / Consent issues
- Response / participant rate – adjustments?
- Non participants / refusals – characteristics?
- Compliance / drop outs / losses to follow up
- Impact on endpoints / data analysis?
Outcome of Interest

- **Primary Endpoint**
  - What is it?
  - Can it be defined precisely?
  - Can it be measured?
  - How do you plan to measure / document it?

- **Secondary Endpoints**
  - Are there any?
  - If **yes**, how many? (too many?)
  - If **no**, should there be?
Methods of Evaluation - I

**Baseline / Follow-up**

- Measure the same parameters in the same way at baseline and follow up
- Standardize to reduce measurement error
- Develop SOP’s appropriate to the study
- Decide frequency of follow up measurements
- Advise caution re analysis of repeated measures in same individuals
Methods of Evaluation - II

**Subjective / Scaling methods**
- Use pre-existing, pre-tested instruments
- Estimate validity and reliability

**Objective / Validity and Reliability**
- Standardisation / calibration
- Measures of validity / accuracy
- Measure of reliability / reproducibility
Basic Data Management: Some truths

Most (first-time) Researchers:

● Know they should write a Research Protocol before starting a project
● Can guess the key elements of a Research Protocol even without a Template
● Really don’t think too much about the data required, i.e.
  – what data to collect
  – where to get / collect the required data
  – how to collect the required data
  – what to do with them once collected
● Shudder at the thought of Data Analysis / Statistical Tests!
Basic Database Management: Some truths

Most (first-time) Researchers:

- **At best**, give some thought to how to handle project data but find it too uncomfortable / difficult to deal with
- Decide to ‘cross that bridge when they come to it’
- Muddle along somehow in the hope that out of a ‘soup’ of figures will emerge some results
- Plan to find a friendly Statistician at a late stage in the process
- **At worst**, do not think about it until it’s too late or not at all!
Basic Data Management: Elements

1. What Data?
2. Where to find them?
3. How to collect them?
4. How to ensure consistency in data collection?
5. How to collate data electronically?
6. How to ensure integrity (validity) of data in database?
7. How to ensure integrity (security) of data in database?
8. How to analyse, interpret and report findings?

In so far as possible all aspects should be addressed and planned for at the before the project begins
Basic Data Management: Elements

1. What Data?
   - Decide what Data Items (Variables)
     - Group Items / Variables into Categories
       - Administrative
       - Demographic
       - Attitudinal / Behavioural
       - Clinical
       - Economic
       - Occupational

2. Where to Find?
   - Sources of Data (Primary / Secondary)
     - Public domain (e.g. Vital Stats, Registry Data)
     - Requests from existing databases (e.g. ESRI / HIPE)
     - Records available (e.g. Company, Medical)
     - ‘New’ data (e.g. questionnaires, clinical data)
3. How to Collect Data?

4. How to ensure consistency in Data Collection?

(QA in data collection)

- **Standardised Format**
  - Questionnaire
  - Case Report Form
  - Spreadsheet

- **Standardised Terminology**
  - Data Dictionary to include the following on each variable
    - Full Name & Abbrev to be used
    - Definition
    - Source(s)
    - Type (Quantitative/Qualitative)
    - Type (Continuous/Discrete/Categorical)
    - Level of Measurement
    - Coding Options *(very important)*
A Data Dictionary is a …

- ‘Database’ about a Database
- Centralised repository of information about data
- It catalogues what data are stored
- The characteristics of each data item / variable
- It defines the structure of a database itself, not that of the data held in the database
- There is no universal standard as to level of detail in a Data Dictionary
A Data Dictionary

- Is essential for training study personnel
- Underpins standardisation of data capture
- Facilitates assessment of data quality (QA)
- Ensures adherence to study protocol
- Invaluable at data analysis phase
What’s in Data Dictionary?

For each Variable:
- Column in which entered
- Abbreviation to be used (appropriate & intelligible)
- Full name of the Variable with Unit of Measurement
- Definition of the Variable (complete & agreed)
- Source(s) – where and how to find information
- Type (Quantitative/Qualitative)
- Type (Continuous/Discrete/Categorical)
- Level of Measurement
- Coding Options
5. How to collate data electronically?

- Create a Database
  - Excel / Access / Other
  - Relational / Bespoke

- Enter data to proscribed format

6. How to ensure integrity (validity) of data in your database?

- Standardised Routines for:
  - Periodic review of data entered
  - Identification of errors e.g. missing data, incorrect or illogical entries (the Data Dictionary is critical to this)
  - Correction of errors (data cleaning / editing strategies, possible including review of source documents)
  - Documentation / log of edits made

(QA of database data)
7. How to ensure integrity (security) of data in your database?

- Data Security Measures
  - Care / security of source documents
    - Questionnaires / CRF’s
    - Personal Identification
  - Care / security of hardware
    - PC / Laptop / USB
  - Software security
    - Basic / sophisticated

8. How to Analyse, Interpret & Report findings from your study?

- Statistical Analysis
  - Standard statistical software
  - Standard statistical techniques
Up to 30 allowed

Use a software application which enables users to manage bibliographic references (e.g. Endnote)

References can be entered manually or downloaded from an online database

Endnote can format them according to the requirements set out for your thesis

http://www.ucd.ie/library/students/information_skills/endnote/index.html
As relevant:

- Participant Information Leaflet
- Consent Form
- Research Ethics Committee Approval
- Questionnaire
- Focus Group Interview schedule
- Case Report Form for data collection
- Data Dictionary