



### Protocol components

A research protocol is a separate document clearly describing the science, objectives and ethics of the project.

#### **The scientific aspects of the protocol should include a discussion of;**

- the research problem and background analysis
- the relevant literature including animal and adult literature (where appropriate)
- study objectives
- the research design and methodology
- study population (including control populations if applicable) to be used (inclusion/exclusion criteria)
- proposed study endpoints
- ascertainment/measurement methods for evaluating study endpoints
- a schematic timeline when the protocol proposes multiple interventions or multiple time points
- statistical plan including hypothesis and proposed sample size
- definition of adverse and serious adverse events

#### **The ethical aspects of the protocol should include a discussion of;**

- potential benefits to participants and others
- potential harms to participants and others
- how potential harms will be minimized - including the risk of breach of privacy and confidentiality
- alternative treatments or procedures
- the document and process for seeking consent and assent