

# TITLE OF THE PROJECT

Names of the investigators

Affiliations

# BACKGROUND

- Defining the problem
- What is already known
- Need for the present study

# AIMS AND OBJECTIVES

- AIMS
- OBJECTIVES

# METHODOLOGY

- SUBJECTS
  - Inclusion & Exclusion criteria
  - Source of Subjects
- DESIGN
- ASSESSMENTS
- INTERVENTION
  - (One can have 4 separate slides for these heads)

# ETHICAL CONSIDERATIONS

- Subjects
  - Informed consent form (translated version to other languages if applicable)
  - Freedom to withdraw from the trial if necessary
  - Any financial implications (if patients have to spend for assessments, travel, printing questionnaires etc.)
  - How do you ensure the confidentiality of the data
- Assessments
  - Method of investigation (invasive/ non-invasive)
  - Time taken for investigations and frequency of repetition

# ETHICAL CONSIDERATIONS

- INTERVENTIONS
- Test intervention:
  - Standardization
  - Supporting evidence
  - Safety
  - Feasibility
  - Withdrawal criteria
- Control Intervention
  - Is this the conventional line of treatment?
  - Who will decide the treatment regime
  - How do you supervise the group

# ETHICAL CONSIDERATIONS

- Are the subjects covered under any insurance scheme
- How do you manage complications if any
- Any conflict of interest for the funding agency
- Authorship related:
  - Contributions of investigators