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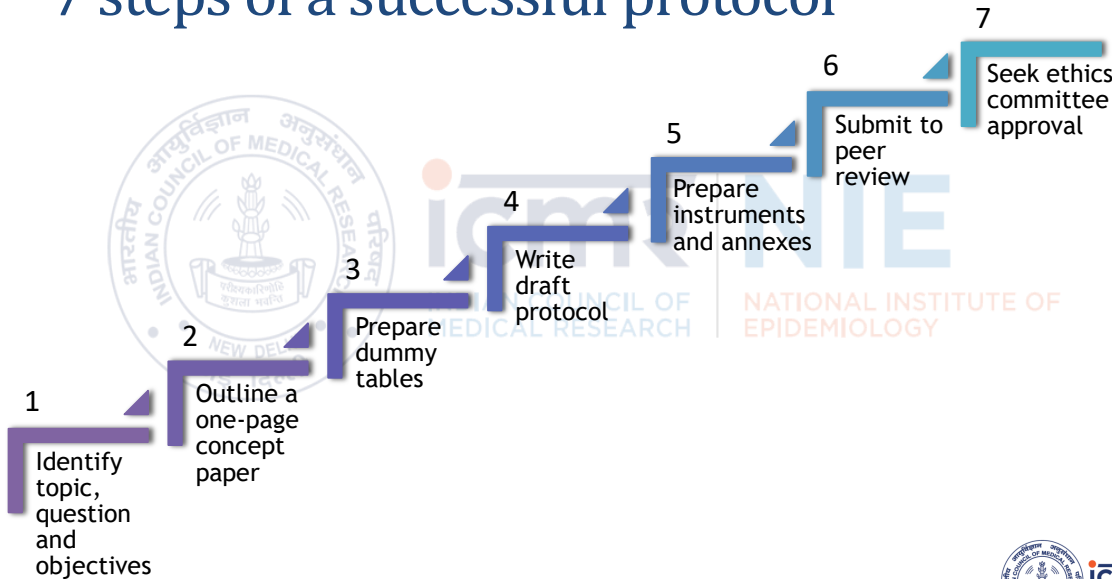
Elements of a protocol for research studies

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7 steps of a successful protocol



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The first draft of the protocol

- Thought as it is written
- Keeps concept paper as summary
- Uses the concept paper outline
 - Background/justification
 - Objectives
 - Methods
 - Expected benefits
 - Budget
- Does not exceed 2000 words
 - Introduction < 20% of length
- Contains 5 – 10 key references



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Outline of the methods section

Study design	
Description of interventions (experimental studies)	
Study population	
Operational definitions	
Sampling procedure	
Sample size	
Data collection	
Analysis plan	
Project implementation plan (Quality assurance)	
Human subjects protection	



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Study design paragraph

- Explains how the objectives lead to indicators and to the study design
- Describes the type of study
 - Experimental
 - Cohort
 - Case control
 - Cross sectional
- Describes logistical arrangements
 - Prospective
 - Retrospective



Description of the interventions

- Applicable if an intervention is planned
 - Clinical trial
 - Community intervention
- Describes the “treatment” applied to the intervention and control group
 - Who?
 - What?
 - When?
 - How?



Study population paragraph

- Use time, place and person:
 - Inclusion criteria
 - Exclusion criteria
 - May be added as a separate section but do not differ conceptually from the inclusion criteria
- Do not confuse the study population and the study sample
- Ensure that the study population is suitable to address the objectives



Operational definitions paragraph

- Spells out and justifies
 - Key outcomes
 - Key exposures
- Clarity and specificity essential
- References, if applicable



Sampling procedure paragraph

- Describes and justifies
 - The type of sample used
 - Convenience sample (Avoid if possible)
 - Random sample
 - Systematic sample
 - Cluster sample
 - The way the sample will be selected in practice
- Provides references, if needed
- Explains randomization, if applicable



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Sample size paragraph

- Details all parameters used to estimate the sample size
- Explains how the estimate was generated
 - Software used
 - Formula used
- Provides references, if needed



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Data collection paragraph

- Lists the data that will be collected
- Specifies how the data will be collected
 - Who?
 - How?
 - Type of instrument to be used
 - Type of data collection method

The analysis plan paragraph

- Data entry
- Software used
- Recoding stage
- Descriptive stage
 - Prevalence, incidence
- Analytical stage
 - Univariate
 - Stratified
 - Multivariate analysis

Project implementation plan paragraph

- Details the steps that will be used to ensure data quality at all stages
- Addresses
 - Data collection
 - Data entry and analysis
 - Reporting
 - Roles and responsibilities of investigators
 - Project governance
 - Coordination of project activities
 - Project timeline



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Human subjects protection paragraph

- Explains the steps that will be used to protect the study participants
- Addresses
 - Minimization of risks (Confidentiality)
 - Maximization of benefits
 - Compensations (without undue incentive)
 - Informed consent
 - Approval procedures (Ethics committee)



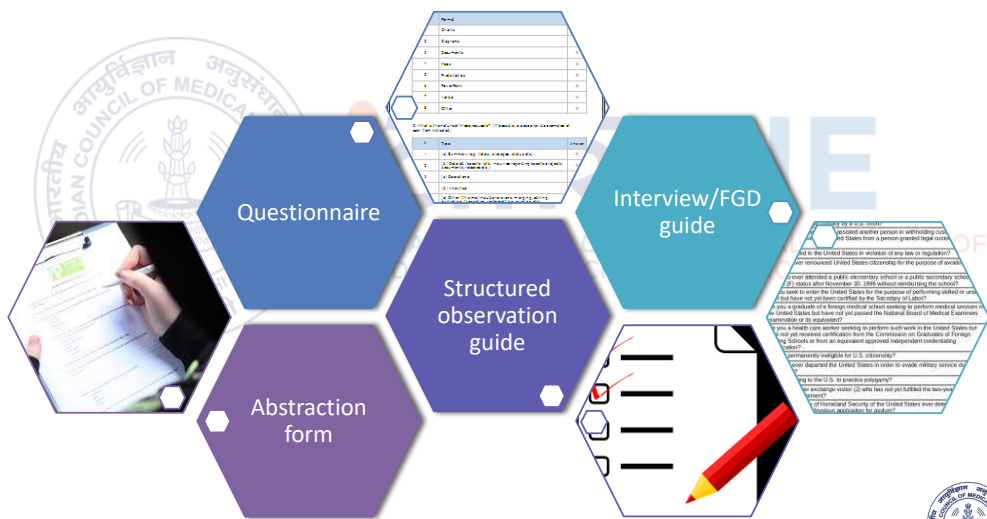
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Data collection instruments



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Annexes

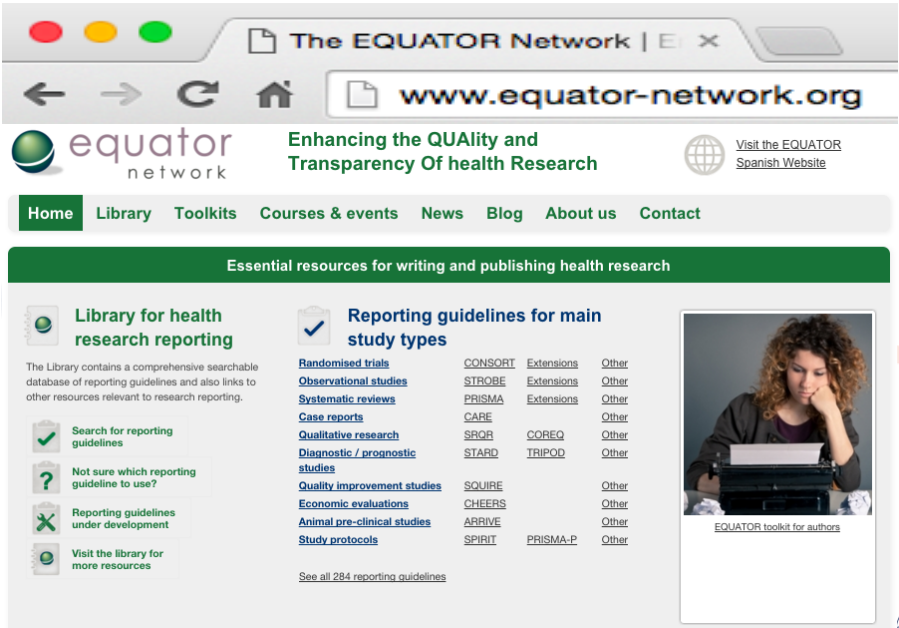
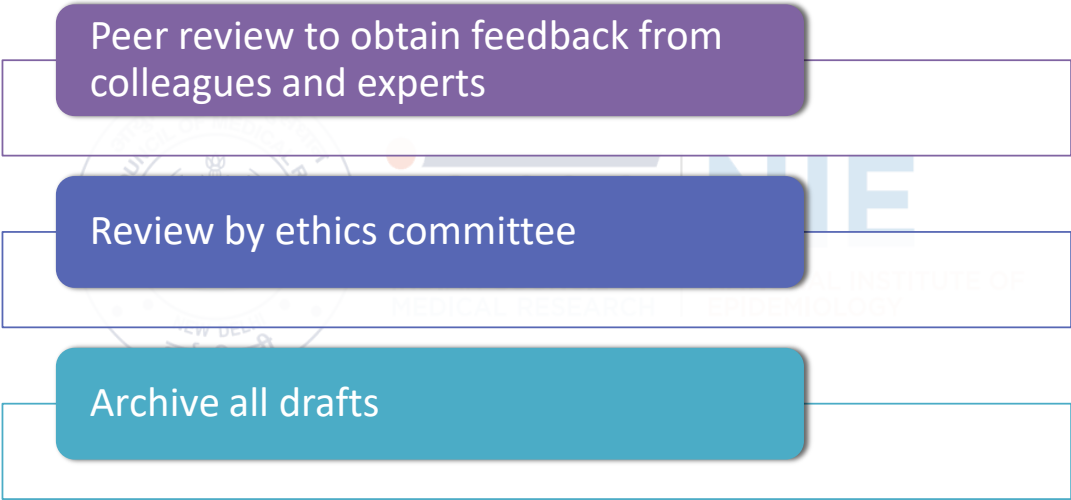


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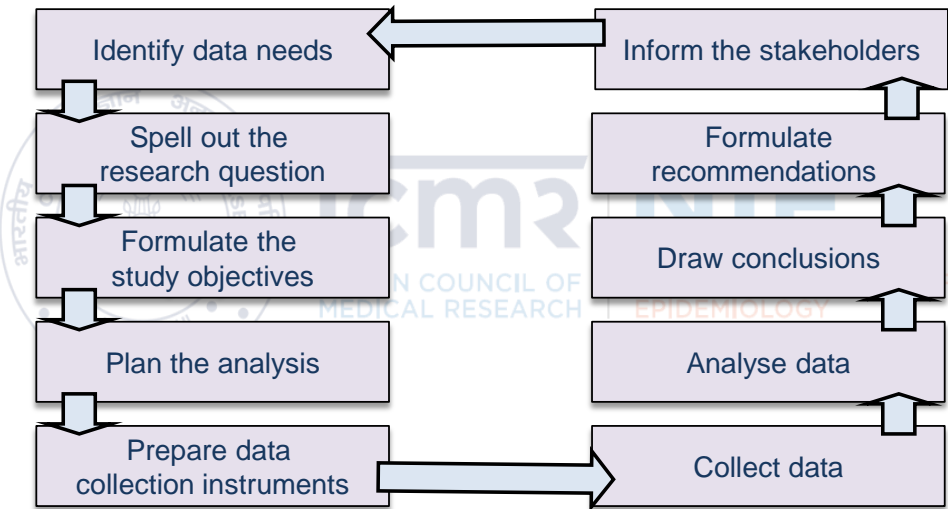
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Finalizing the protocol



The life cycle of research



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Thank you

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