

Planning a Research Project – Questions to Ask

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The Protocol

What is the purpose of the project?

- ❖ What are its aims and precise objectives?
- ❖ What questions is the project intended to answer?
- ❖ Is the purpose to test, examine, or evaluate current practice or a new treatment, procedure, service, or to obtain new facts about the causation or natural history of a disease?

What is already known about the issues to be investigated?

- ❖ What are the gaps in the present knowledge?
- ❖ How will the proposed project contribute to knowledge and understanding of the problem?
- ❖ What might be the applications in practice of the results of the study and how may this be achieved?

Is the proposal for a pilot or for a main study?

If a main study is proposed, the details of the pilot study should be included in the proposal.

What design will be used in the project?

- ❖ Will the project be basically a laboratory study, a clinical trial, or a survey?
- ❖ Will it be a trial of an “intervention” – for example, a treatment, procedure, or service? These could be therapeutic, preventive, caring or educational?
- ❖ Will it be a case-control study with randomised or matched controls, or a quasi-experimental study?
- ❖ If a survey, will it be conducted by use of questionnaires, interviews, or clinical examinations?
- ❖ Will the study be retrospective, cross-sectional, or prospective?
- ❖ Is it a “blind” or “double-blind” design proposed?

How are the subjects of the projects to be chosen?

- ❖ What is the population from which the subjects will be drawn?
- ❖ Are the subjects of the project the total population of a community or all patients with a certain diagnosis, impairment, or disability?
- ❖ What are the entry and exclusion criteria for selecting subjects for a study?
- ❖ How are the controls to be chosen?
- ❖ Will a sample of the total population or of all potential subjects be used?
- ❖ If so, how is the sample to be obtained to ensure that it is representative of the total group?

What data are to be collected, and why?

- ❖ What factors (variables) are already thought to affect the outcome?
- ❖ What new factors are being tested in the study?
- ❖ What extraneous factors, if presented, might distort the general representativeness of the results?
- ❖ What are the indicators or measures of the outcomes of the trial or experiment?

What are the treatment schedules or other activities forming the “intervention” in the project and how are the variables to be defined and measured?

- ❖ Have the techniques, dosage, programmes of treatment, prophylaxis, and other activities been standardised? (This is especially important in multicentre studies)
- ❖ Have explicit decisions been taken about (a) how the presence or absence of disease is to be determined (for example, hypertension and diabetes), (b) how duration and severity are to be measured, and (c) how social and demographic variables (for example, marital state, occupation, socio-economic group, and ethnicity) are to be defined?

How are the data to collect and the measurements to be made?

- ❖ Will the data be collected from records, observations, interviews, or examinations of the subjects?
- ❖ Will special recording forms be needed?
- ❖ Who will collect the data?
- ❖ What training will they need and how will this be arranged?
- ❖ Should an independent observer make the baseline and/or outcome measures?
- ❖ Have the methods been tested?
- ❖ Are they valid: do they actually measure what they are intended to?
- ❖ Are they reliable: Can they be repeated to yield the same results?
- ❖ Are they sensitive: can they identify only positive cases?
- ❖ Are they specific: can they identify only positive cases?
- ❖ What checks and controls will be used to maintain accuracy and objectivity during the collection of the data?

How will the data be processed and analysed?

- ❖ What statistical and computing help is required?
- ❖ What is available?
- ❖ Will any of the data have to be coded?
- ❖ If so, who will do this?
- ❖ Who will do the data entry?
- ❖ How will the analysis proceed?
- ❖ How will the results be presented?
- ❖ What will be the form of the report?

Are there problems of ethnic or etiquette associated with the project?

- ❖ Are patients'/subjects' rights properly protected?
- ❖ How are the consent and collaboration of patients, interviewees, doctors, nurses, social workers and other to be obtained?
- ❖ How is the confidentiality of the data to be ensured at each stage of the project?
- ❖ What agreements will be made about publication of the data and the report?
- ❖ Has the project been approved by the relevant ethics committee?

What arrangements are to be made for advising or treating people for whom new needs come to light as a result of the project?

- ❖ Can the local services cope?
- ❖ Have they been advised about the project?
- ❖ Will special arrangements be required?

What is the timetable for the project?

- ❖ In what order will the different stages of the project be carried out?
- ❖ What is the duration of each stage?
- ❖ Who will be involved at each stage?

What will the project cost?

- ❖ What will be the cost of each stage of the project?
- ❖ What will be the cost in workforce, including the estimated costs of the time of the main investigator, advisor, and others not directly employed for the project?
- ❖ What will be the cost of additional salaries, including pension and national insurance contributions?
- ❖ What will be the cost of the rent for the accommodation for the project?
- ❖ Is capital equipment required?
- ❖ What is the estimated expenditure on travelling and subsistence, stationary, printing, postage, telephone and photocopying?
- ❖ Are there computing costs?
- ❖ What outside help and advice are needed?
- ❖ What are the administrative costs and overheads?
- ❖ What are the possible costs to the NHS or other organisation involved in the project?