

MODULE

2

**DEVELOPING AN
IMPLEMENTATION
RESEARCH PROPOSAL**

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ABBREVIATIONS

ACT	artemisinin-combination therapies
ANC	antenatal care
ART	antiretroviral therapy
BCC	behavior change communication
BMI	body mass index
CAS	complex adaptive system
CHW	community health worker
CMS	Cooperative Medical Scheme
COS	Community of Science
DOT	directly-observed therapy
ERC	ethics review committee
FGD	focus group discussion
HDI	Human Development Index
HIV	human immunodeficiency virus
HRP	Special Programme of Research, Development and Research Training in Human Reproduction
IC	informed consent
ICF	intensified case finding
IDRC	International Development Research Centre
IEC	information, education and communication
IKT	integrated knowledge translation
IR	implementation research
IRB	institutional review board
IRP	Implementation Research Platform
KT	knowledge translation
KZN	KwaZulu-Natal
LLIN	long-lasting insecticide-treated net
LOI	letter of intent
LSHTM	London School of Hygiene and Tropical Medicine
LTFU	loss to follow-up

M&E	monitoring and evaluation
MDR-TB	multidrug-resistant tuberculosis
NGO	nongovernmental organization
NSF	National Science Foundation
NTBCP	national TB control programme
OER	Office of Extramural Research
PI	principal investigator
PLHIV	person/people living with the human immunodeficiency virus
PMTCT	prevention of mother-to-child transmission
QDA	qualitative data analysis
RFP	request for proposals
SAGE	Strategic Advisory Group of Experts
SARS	severe acute respiratory syndrome
SMART	specific, measurable, achievable, realistic and timebound
SOP	standard operating procedure
SWOT	strengths, weaknesses, opportunities and threats
TB	tuberculosis
TDR	Special Programme for Research and Training in Tropical Diseases
UNDP	United Nations Development Programme
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
WHO	World Health Organization

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INTRODUCTION

The purpose of this module is to support you and your team to develop a high quality implementation research (IR) proposal so that you can be competitive in securing research funding.

If you are setting out on developing an IR proposal and are not sure where to start, you are not alone! Even defining the research question can at first seem overwhelming. This module has been designed to help team members understand and conduct the basic processes involved in writing an IR proposal.

After completing this module, participating research teams will be able to complete their IR proposals.

The content and activities in this module are organized into five sessions, with each addressing a specific section of an IR proposal in a stepwise way. Each session consists of the following elements:

- *Learning objectives*: identifying what you will accomplish by the end of each session.
- *Content presentation*: providing you with the information necessary to understand the specific aspects of proposal writing.
- *Activities*: exercises facilitating the understanding of the content and putting theory into practice.
- *Group work*: discussions providing an opportunity to ask questions, and consider specific issues in relation to your specific project.
- *Write-shops*: provides an opportunity to work together each evening in drafting elements of your research proposal, as covered each day.

The workshop will be facilitated by researchers experienced in IR, who will guide and support you during the process of developing your team's IR proposal.

The module also provides harmonized guidelines for proposal development to train researchers from different backgrounds.

Pre-workshop preparation

This module is organized into three stages: before, during and after the workshop (Figure 1).

Before the workshop, you should have completed an online component that introduces key terminology, core concepts, research frameworks, programme components and appropriate questions. The online course takes approximately three hours to complete and its specific objectives are:

- Identifying characteristics of IR.
- Describing implementation/scale up and relating IR to these processes.
- Classifying research questions and associated research that falls under the umbrella of IR.
- Summarizing framework characteristics and identifying strategies for applying them to IR.
- Recognizing how IR is applied to different implementation problems.
- Classifying IR priorities for grant applications.
- Reviewing the roles of various stakeholders and identifying appropriate means for integrating stakeholders in planning and in communicating and disseminating results.

The on line component is available on line at <https://training.measureevaluation.org/certificate-courses/ir>. You should also have completed an initial stakeholders consultation (module 1) as well as literature review to enable you to put your IR problem in to a broader context.



Figure 1. Three stages of the current module

Introduce your team and research challenge

From earlier modules, you may already have a good understanding of what IR is and how this IR approach can help meet your research objectives. You have also likely identified some of the members of your IR team, established each member's roles and responsibilities, and identified a research problem for which you would like to develop a proposal.

To get started, one member of your team will be asked to briefly describe the research problem/ challenge your team is developing a research project to address.

Then invite each member of your team to introduce themselves and explain their ongoing work, as well as roles and responsibilities in your planned project.

Group activity: Refresher on IR fundamentals

Organize into small groups. Ideally, members of each team should split into different groups. Each group is assigned one of seven topics (see slide). In individual groups, prepare a two-minute presentation summarizing your assigned topic, drawing on content from the pre-workshop online component/ previous modules.

Choose a spokesperson to present your key points in plenary (in two minutes).

Funding an IR project

There are essentially three types of funding agencies that are potential sources of support for research projects:

- Multilateral organizations

- e.g. WHO, World Bank, United Nations Children's Fund (UNICEF), United Nations Development Programme (UNDP), European Commission, and special programmes such as TDR, the Alliance for Health Policy and Systems Research and the Special Programme of Research, Development and Research Training in Human Reproduction (HRP).

The Alliance, TDR and HRP, as designated research programmes, periodically issue calls for health research proposals, including those focused on IR. Most multilateral organizations have developed implementation programmes in low- and middle-income countries of which part of programme budget is allocated for monitoring and evaluation, as well as implementation research.

- Bilateral donors
 - e.g. Canada Government, United Kingdom Government (DFID), United States Government (USAID, National Institutes of Health, Fogarty International Center), Norway Government (Norad), Sweden Government (SIDA) Australia Government, and the International Development Research Centre (IDRC).

An increasing number of bilateral organizations, such as IDRC, NIH/FIC DFID, USAID, and NORAD have supported implementation research. Almost all the bilateral organizations have aid projects/programmes in low- and middle-income countries of which a certain percentage of the programme budget is allocated for monitoring and evaluation, as well as implementation research.

- Private foundations and trusts
 - e.g. Gates Foundation, Rockefeller Foundation, Ford Foundation, Wellcome Trust.

Private foundations and trusts have a tradition of supporting health research, among other issues. Implementation research is one of the areas where some private foundations and trusts have gotten interested in supporting. Note that this list of examples is not exhaustive. National governments in low and middle income countries also fund research to improve access and delivery of interventions within their health systems.

Find a match

To find a good match for your proposal, consider:

- your level of experience;
- the resources/funds you need;
- timing and deadlines;
- your location;
- who is interested in the topic.

Related resources

Government grants:

- NIH Office of Extramural Research (OER) Grants Guide (<http://grants.nih.gov/grants/guide/index.html>)
- National Science Foundation (NSF)
- Other individual government agencies
- Grants.gov (www.grants.gov) – portal collecting funding/application information from all United States government agencies
- Ministries of health
- National medical research councils

Private associations or foundations

- Foundation Center Directory (Free Library)
- PA Foundation Directory (Free Library)
- GrantsNet – from American Association for the Advancement of Science (AAAS)
- Bill and Melinda Gates Foundation
- Doris Duke Foundation

Subscription databases like the ones listed below provide information on sources of research funding. (government and non government)

- Community of Science (COS)
- InfoEd (Spin/Genius)
- Others (IRIS, Egrants)

Do your searching...

- Go to a library that has good internet access.
- Talk to your institution's Office of Research Administration, if you have one.
- Search comprehensive databases such as COS, eRACOMMONS and Spin.
- Set up alerts from your database searches.
- Search US government grant websites such as OER or Grants.gov, or individual agency websites.
- Search association and foundation websites.
- Find out what projects related to your area were already funded.

This is a very important aspect of your work. If you have some experience in searching databases, you can proceed, otherwise ask for help from a library in or outside of your institution. Whatever approach you take, there are basic steps that you have to follow and several things to consider when deciding where to submit your IR proposal for funding.

Find out which funding opportunities are offering research calls or requests for proposals (RFP)/ letters of intent (LOI). This is important as often they call for applications is once a year. Therefore, planning ahead and working back from the application deadline is important. If you miss the deadline it could be a year until another competition or opportunity arises. In implementation research, a 12 month delay is significant.

In addition to regular RFP/LOI invitations, some funding agencies may also be interested in supporting IR in accordance with their health research strategies. In other words, researchers from low- and middle-income countries could play a proactive role by sending short research proposals for their consideration. Some funding agencies are more interested to commission or solicit health research proposals, based on their mandates and strategies.

You need to ensure a good match between the funding agency and your research project, with regard to research topic, size of grant, geographic region, partners' eligibility, participating countries, required affiliations etc. Explore research that has already been done on the topic to ensure you are not duplicating existing work. Assess the types of projects the agency has funded in the past, so you can extend or compliment these activities. Demonstrate that you have done your homework and are aware of what exists on the topic, identify the gaps and justify what needs to be done and how the findings will benefit the community.

Preparing your application

- Read the instructions for submitting a proposal carefully

- Refer to pertinent literature
- State rationale of proposed investigation
- Include clearly presented tables and figures
- Present an organized, lucid write-up, including as much detail as possible
- Request pre-review from experienced researchers
- Use the style and elements required by the funder's specifications

When applying for a research grant, take advantage of the resources available to you. Most universities in Europe and North America have an Office of Research with trained staff to assist researcher with large grant applications. This may not be available in institutions and health agencies in low and middle income countries, however there may also be many resources available on the Internet that can be helpful. It is important to visit the website of the funding agency to which you plan to submit your proposal. They will usually have full instructions on what to do and when to submit your proposal.

For example: NIH Grant Writing Tips: http://grants.nih.gov/grants/grant_tips.htm. *Reviewers will be looking for projects that make a significant impact on the community or state of health care services offered.*

You can also explore the possibility of communicating with the project manager in the funding agency to obtain more clarity on the application process. Reviewers will look for clear, innovative and exciting ideas, clarity and brevity of writing and realistic objectives and timelines. They will expect a clean, well-written application that promises outcomes that are useful to the population.

What reviewers look for

- Significance and impact – this is very important in implementation research
- Exciting ideas
- Ideas they can understand – avoid assuming too much knowledge or familiarity
- Realistic aims and timelines – do not be overly ambitious
- Stay brief with widely known information
- Note the limitations of the study
- Prepare and submit a clean, well-written application with a justifiable budget

Depending on the funding agency, reviewers may be looking for varied things in different proposals. It is always useful to refer to the instructions in the call for applications before submitting the proposal.

In general, IR proposals are typically rated on the basis of scientific merit and policy relevance using a specific scale (e.g. a 1–5 scale, where 1 is high and 5 is low). Ratings for both categories may be averaged together for a final score, which may be one of the main determinants of the funding decision. Specific criteria that are frequently used in each of these categories are outlined below.

Scientific merit and policy relevance

- Scientific 'soundness'
- Synthesis of existing knowledge (which could include a literature review) – make it concise; pertinent; complete; appropriate
- Research questions – make them appropriate and feasible
- Analytical framework – apply as appropriate and make it sound
- Proposal should be in accordance with IR principles outlined in the call for proposals

- Proposal should address issues relevant in the country/community where the research would be conducted
- Proposal should fit the specific call for proposals

Methodology

- Is the design feasible and appropriate?
- Are data collection methods and tools appropriate for the design?
- What is the sampling method, and size?
- How is data management and analysis planned?
- Is the overall time plan realistic?

Other considerations

- Ethical considerations.
- Critical assumptions.
- Innovation and originality.
- Programmatic practicality.

Additional critical issues

- Is team expertise appropriate for the proposed study?
- Could the project findings be scaled up?
- How generalizable will the results be?
- Is a multidisciplinary approach proposed?
- Will the study foster collaboration and team work?
- Is the budget appropriate?
- Utilization and dissemination possibilities/potential impact on policy and programmes?
- Is there potential for research capacity building/strengthening? This could be important to some funders because it could enhance sustainability of an IR culture in the health system.

Common problems with applications

The following common problems/pitfalls with research proposals should be avoided.

- Lack of new or original ideas.
- Absence of an acceptable scientific/public health rationale.
- Lack of experience in the essential methodology. Lack of sufficient detail on the methodology.
- Lack of relevance to policies, programmes and projects.
- Diffuse, superficial or unfocused research plan.
- Lack of knowledge of relevant published work.
- Unrealistic amount of work required.
- Uncertainty concerning future directions.
- It is helpful to ask the question “So what?” – What difference will the results from the research make to the health system and population if applied.

Components of an IR proposal

In general, the proposal structure is similar for all research.

What is a research proposal?

- A document that describes:
 - the proposed research
 - why it is being conducted
 - the research design

- the expected impact
- A proposal is a requirement for most grant applications, which are typically judged by a committee. To be effective, you need to know:
 - what you are doing;
 - why you are doing it;
 - when you plan to do it;
 - how you plan to do it.

If you have ever written a thesis as part of your studies, you will remember that you were required to write a research proposal and have it 'approved' by a thesis committee and your supervisor prior to applying for ethical clearance (if using human subjects) and beginning your data collection.

When developing an academic proposal, the intent is to generate new knowledge and ideas. Conversely, when developing an IR proposal the intent is to generate research evidence to inform policy and improve programme implementation.

Most grant applications require you to write a research proposal that will be evaluated by a committee to determine if the proposal is worthy of funding.

Writing a research proposal is probably one of the most difficult stages of research. In order to write a proposal, you have to know what you are doing, why, when, and how. You need to develop research question(s), a rationale for why the study is necessary and important, and a conceptual framework. You need to conduct a review of existing literature. You need to design the research and specify what research methods you will be using to collect and analyse your data.

What is different about an IR proposal

IR proposals may differ from conventional research proposals in relation to the:

- origin of the research problem
- involvement of the end users in the research process

These differences arise from the need for IR interventions to help:

- better inform health care service quality improvement efforts
- facilitate uptake by end users
- generate 'generalizable' knowledge so it can be applied across settings and contexts
- engage multiple sectors, e.g. including epidemiology, social science, anthropology, communication science and health economics
- develop policy recommendations and practical solutions

Because it can take years for research findings, guidelines and best practices to be completely integrated into practice, researchers, decision-makers and practitioners constantly seek improved knowledge transfer processes.

To address this challenge, IR originates with a problem identified and prioritized by end users. Encouraging end-user uptake of research results requires end-user engagement in all steps of the research process, including proposal development.

To be effective, IR research findings need to be usable within the available health system framework and implemented appropriately so that end users are able to benefit. IR also aims to produce generalizable knowledge so it can be applied across various settings and contexts (although they may be intervention specific).

Characteristics of an IR proposal

- Each funding agency has its own proposal format and requirements.
- Requirements vary and not all agencies will require all components included in this session.
- Some agencies may require a letter of intent (LOI) as a preliminary screening to ensure your proposal will align with their needs.
- LOI include the same components as a research proposal but with less detail.

Additional characteristics may include the following:

- Clear distinction between routine disease control and systematic study and analysis of issues.
- Indicators to measure outcomes.
- A focus on a limited number of priority areas, rather than focusing on a large number of small isolated issues that are unlikely to have significant health impact.
- Possibility to extrapolate to other settings and diseases.
- Active link to disease control.
- Partnership and link up with other ministries, departments and agencies.
- Involvement of mentoring train the young and involve the experienced.
- Involvement of health professionals from the study setting.
- Active dissemination of results at all levels of implementation.

The components of a research proposal may vary slightly depending on the purpose outlined by the funding agency to which it is being submitted. Many funding agencies indicate specifically what should be addressed in the proposal.

As each funding agency has its own format and requirements, some of the elements covered in this module may not be required in every research proposal.

Components of an IR proposal

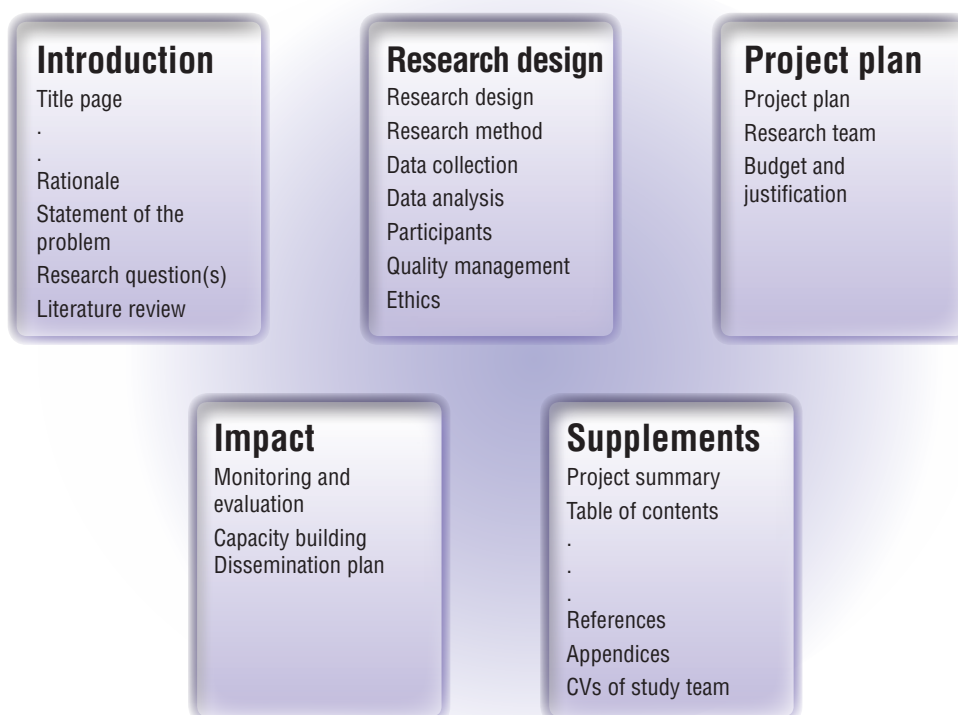


Figure 2. Components of an IR proposal

This session has been designed to be general enough so it can be adapted to fit the priorities of different users and funding agency calls for proposals. Below is a list of common components of IR proposals:

- **Introduction:** containing title page, rationale, statement of the problem, objectives and research question(s), and literature review (synthesis of existing knowledge) (Table 1).
- **Research design:** outlining participants, research methods, data collection, data analysis, quality management and ethics (Table 2).
- **Project plan:** containing project plan, research team and budget (Table 3).
- **Impact:** including monitoring and evaluation, capacity building plan and dissemination plan (Table 4).
- **Supplements:** including project summary, table of contents, references, appendices and CVs of investigators (Table 5).

Introduction

The introduction to your proposal includes the title page, project rationale/summary, table of contents, rationale, statement of the problem, objectives and research question(s), and a review of the literature (synthesis of existing knowledge).

Table 1. Sub-components of introduction section

Section	Description
Title page	<ul style="list-style-type: none"> • Four components of a good title: <ul style="list-style-type: none"> – Use action words. – Reflect implementation and intervention themes. – Include specific target populations (adolescents, children under 5 years of age etc.). – Include specific geographic location(s).
Rationale	<ul style="list-style-type: none"> • Outlines what is being studied and why. • Summarizes expected outcomes, including the anticipated impact(s). • Provides clear succinct rationale for why the project should be funded.
Statement of the problem	<ul style="list-style-type: none"> • Summarizes the purpose of the study. • Is a paragraph rather than a single statement. • Establishes the direction and captures the essence of the study. • Is clear and concise. • Incorporates your general objectives and uses action words to succinctly outline the purpose of the study. • Reflects the research design of the study. • Leads logically to the research question(s).
Objectives and research question(s)	<ul style="list-style-type: none"> • Should be of interest to the research community, researchers, policy-makers; decision-makers, funding agencies, and the health care providers the research will ultimately affect. • Should be answerable. • Are shaped by the problem, and in turn should logically influence the design of the research. • Are clear and specific. • Are feasible.

Section	Description
	<ul style="list-style-type: none"> • Provides information required to evaluate ongoing interventions or progress. • Analyses possible causes for missed targets in order to find solutions. • Answering the question will result in important information.
Literature review	<ul style="list-style-type: none"> • Demonstrates familiarity with the topic. • Summarizes what is not known about the topic. • Establishes credibility. • Places proposed research in a broader context. • Demonstrates relevance by making connections to a body of knowledge. • Integrates and summarizes what is already known about a topic.

Research design

The research design section includes: research design, research methods, data collection, data analysis, quality management, and participants and ethics.

Table 2. Sub-components of research design section

Section	Description
Research design	<ul style="list-style-type: none"> • Describes the nature or structure of the research. • Describes whether it is qualitative, quantitative or mixed methods; between- or within-subjects; experimental or correlational; individual or collective case study etc.
Research method	<ul style="list-style-type: none"> • Comprises the various methods you will use to obtain and analyse data. • Justifies what you will do when and how. • Provides a rationale for your research design. • Justifies how your methodology will enable you to produce results that are new or unique. • Comprises a number of sub-sections such as research design, participants, data methods, data collection, and data analysis.
Data collection	<ul style="list-style-type: none"> • Explains how you intend to gather the information that will be used to answer the research question(s). • May involve the use of quantitative (e.g. surveys, recording the number of times an incident occurs, laboratory experiments), qualitative (e.g. interviews, observations).
Data analysis	<ul style="list-style-type: none"> • Describes exactly how you plan to compile the data you collect and how you will organize and interpret the data to make sense of what you find. • Identifies themes, developing tables and charts, identifying relationships, and/or calculating frequencies.
Participants	<ul style="list-style-type: none"> • A full description of the subjects (sample) or participants involved in the research. • How participants will be selected. • Criteria for becoming a participant.

Section	Description
Quality management	<ul style="list-style-type: none"> • System to ensure the quality of the research project. • Helps provide confidence that the conduct of the study and data generated optimally fulfill applicable requirements. • NOT OPTIONAL – You must have a quality management plan.
Ethics	<ul style="list-style-type: none"> • You must apply to an ethics board/committee if you will collect information/data from human participants (directly or indirectly). • If you are collecting data in more than one site you may need to apply to more than one board. • Stipulate that you intend to apply for ethics approval. • Ethics approval may take several months to receive, so apply as soon as you submit your proposal for funding. • Most agencies will not release funds until ethics clearance has been received in writing.

Project plan

The project plan includes: Project plan, research team, and budget.

Table 3. Sub-components of project plan section

Section	Description
Project plan	<ul style="list-style-type: none"> • Presents a clear indication of the timeframe for the project and the times when each aspect of the project will be implemented. • Often a work plan or timeline is displayed most effectively in a graphic, table or Excel sheet. • Will help demonstrate the feasibility of the project in a very visible way. • Identifies tasks; when the activity will take place; and by whom.
Research team	<ul style="list-style-type: none"> • Describe the members of your team and the experience/assets they contribute to the project. • Team must be multidisciplinary and diverse (depending on the nature of the research, it may include members of the community as well as researchers, healthcare providers and decision makers). • Convince the reviewers you have enough expertise on your team to conduct the proposed research effectively. • Include the role(s) and responsibility of each individual listed on the project. • Indicate whether team members are involved in a full- or part-time basis.
Budget and justification	<ul style="list-style-type: none"> • Outlines the resources needed to effectively conduct the proposed research. • Outlines exactly what is realistically needed from the funding agency to carry out the project. • Should be realistic in the context of the research setting. • Outlines how much money is needed in each phase of the project. • Aligns with agency suggested/required budget categories. • The budget should align with the proposed activities in the research design.

Impact

The impact section contains the following: monitoring and evaluation, capacity building, and dissemination plan.

Table 4. Sub-components of impact section

Section	Description
Monitoring and evaluation	<ul style="list-style-type: none"> • Describes exactly how the team will decide whether or not the project meets its objectives. • Informs the prospective funding agency how they will be shown at the end of the project that their investment was a good one. • Facilitates the implementation of evidence-based practice and improved health outcomes. • Examines the difference between the implementation effectiveness and the efficacy of health intervention.
Capacity building	<ul style="list-style-type: none"> • How the project can help improve the research capacity of national and local institutions involved, via training, mentorship, etc. • How the project, can help increase capacity for using research evidence for policy or decision-making by key stakeholders, such as government officials, involved in the project.
Dissemination plan	<ul style="list-style-type: none"> • The dissemination plan should include intended publications, newsletters, workshops, radio broadcasts, presentations, printed hand-outs, slide shows, training programmes, etc. • Identify key stakeholders target audience and their needs. • Involve stakeholders throughout the process. • Tailor the message accordingly – stakeholder groups vary by their familiarity with research terminology and preferences for receiving information.

Supplements

Supplements include: Project summary, table of contents, references, appendices, and CVs of members of the project team.

Note that the project summary and table of contents are placed at the beginning of your proposal, but are only written *after* you have completed the other sections.

Table 5. Sub-components of supplementary sections

Section	Description
Project summary	<ul style="list-style-type: none"> • Briefly describes the entire proposal. • Although read first, written last. • Includes a description of the problem under investigation, a rationale (situated in the existing literature) for why the research is needed and/or important, the participants, the methodology, and the implications of conducting the research. • Is your 'first impression' with reviewers and may influence whether reviewers choose to fund your proposal. • Makes it very easy for reviewers to comprehend and evaluate your proposed project according to the review criteria.

Section	Description
Table of contents	<ul style="list-style-type: none"> • Organizes the proposal by outlining 'what' is in it and where each item can be found. • Presents a convenient list of the topics and sections in a logical sequence 'at a glance'. • Word processors automatically place the headings, sub-headings and page numbers for you in a professional manner.
References	<ul style="list-style-type: none"> • Lists all references cited in the text of your proposal (in a recognized referencing style). • If a reference is not cited in the text of your proposal, it should not be listed in your reference list.
Appendices	<ul style="list-style-type: none"> • Include those aspects of your project that are of secondary interest to the reader. • Assume the reader can obtain all the necessary information from the body of the proposal. • May include things such as investigators' CVs, research instruments, or letters of support. • Can provide a place to put additional information you would like the reviewers to have access to, but that the length restrictions prohibit.
CVs of members of the project team	<ul style="list-style-type: none"> • Can have an influence on the reviewer's assessment of your proposal. • Ensure that at least one member of your team has IR experience, a good track record and a strong publication record. • Complementary qualities such as credibility in the community can be equally important. • Agencies usually have a limit of 1–3 pages for an investigator's short CV. • Develop a template to highlight the most relevant aspects of team members' CVs to align with the scope of the funding agency.

In each of the following sessions, your team will develop and write one section of your research proposal.

1. WRITING THE INTRODUCTION SECTION

In this session, you will take the first steps in writing your IR proposal by drafting your introduction section. This involves writing an overview of your research problem and conducting a systematic review of existing materials and literature to provide a rationale for why this problem is important and should be addressed. You will also develop general and specific research objectives, a statement of the problem and your research question(s).

After completing this session, you will be able to:

- Write the introduction for your proposal.
- Develop the research question(s) for your proposal.

Writing the introduction

The introduction to your proposal:

- Outlines what is being studied and why (i.e., the rationale).
- Builds an argument for the current study.
- Includes the statement of the problem, general objectives, specific objectives and research question(s).
- Reviews existing literature.
- Summarizes expected outcomes, including the impact the results will have.
- Provides clear succinct rationale for why the project should be funded.

The introduction is essentially a focused review of the pertinent existing knowledge, including published studies, project reports, and other literature. It builds an argument for conducting the study, including general and specific research objectives, the statement of the problem, and research question(s). This argument or rationale might be based on a need identified by the community, policy-makers, and programme managers. In sum, the proposal introduction provides a clear, succinct description of what the research is and a rationale for why the project should be funded.

Introduction objectives

The introduction provides critical information for funding and community support by accomplishing the following three things:

- Provide a foundation for the further development of the proposal (overview of the problem).
- Facilitate background information on, and reports from, similar studies (systematic analysis and succinct review of literature).
- Systematically state why the proposed IR should be undertaken (rationale), what you hope to achieve (objectives) and expected results (outcomes).

Guidelines for writing the introduction

- Begin by conducting a systematic analysis about the problem you want to research and why it is important that this research is done.
- Once you have your initial ideas clarified, continually edit the introduction as you progress, discuss issues with your team and receive feedback from the larger workshop group and facilitator.

The rationale should indicate why the research should be undertaken including the scientific, public health and policy relevance of the problem to be investigated, as well as the magnitude, frequency, affected geographical areas, ethnic and gender considerations of the problem. The introduction should also list other available options to the research problem and make a case as to why the chosen approach should be researched. It should also indicate how the results will be used and why it is likely to affect health care and health systems/policies, and who will ultimately benefit if the project results are used appropriately.

What to write about

- Overview of the health system and setting (context).
- Description of the nature of the problem.
- Analysis of the different factors that may influence the problem.
- Description of solutions tried (background), and justification for further research.
- Information expected from the research and how this information will be used to solve the problem (outcomes).

To accomplish this, succinctly write about each of the items listed below. Just start writing, do not worry about how your ideas sound initially or perfecting what you write: you will continually change, elaborate, delete and edit the introduction as you progress with researching and discussing the topic provided.

- An overview of the health care system in the country/region/district as these are relevant to the problem. Include illustrative statistics (if and when appropriate and/or available) to describe the context in which the problem occurs.
- A description of the nature of the problem.
- An analysis of the various factors that may influence the problem – why some factors need to be investigated.
- A brief description of any solutions to the problem that have been tried in the past (background), how well they worked and why further research is needed (justification for the study).
- A description of the type of information expected to result from the IR study and how this information will be used to solve the problem (outcomes).

Developing the title

There are four components to a good title:

1. Use 'action' words
2. Reflect implementation and intervention themes
3. Include specific target populations (adolescence, children under five year of age, etc.)
4. Include specific geographic location

The title of a research proposal should describe the study, be concise and inform the reader what the research is about. It should include key words that would also help to identify appropriate reviewers. The title may not differ significantly from that of any other research proposal, but the topic it addresses will reflect a need identified in the community. It is possible that you may also have "Implementation research" in your proposal title if you are applying for a research grant that is specific to IR.

For example:

- Identifying gaps in HIV prevention among adolescents in Sub-Saharan Africa: An implementation research study.

- Using implementation research to explore the rise in under-five mortality rates in Cameroon, Central African Republic, Chad, Democratic Republic of the Congo, Kenya and Zambia.

Rationale

- The introduction must justify why the research problem you have identified is important and worthy of funding.
- To provide this justification, begin by providing evidence through a systematic analysis of existing information.

Information to support your literature review can be found from a variety of resources and locations including:

- local documentation – project progress reports, theses, dissertations, seminar proceedings
- programme progress or evaluation reports
- medical literature, including reviews that outline gaps in research
- scientific meetings and conferences
- new ideas/recommendations from previous research
- funding agencies' annual reports
- questions asked by programme staff and/or students

Example

A major challenge for onchocerciasis control is to deliver annual ivermectin treatment to all target communities and to sustain high treatment coverage over a very long period. To achieve this, the African Programme for Onchocerciasis Control (APOC) has adopted the strategy of community-directed treatment (ComDT) with ivermectin. This strategy has proven very effective. Ivermectin treatment is popular and communities have responded enthusiastically to the concept of a community-directed intervention, in which they are themselves in charge of planning and implementation. A recent external evaluation of APOC concluded that ComDT was a timely and innovative strategy. The communities themselves were deeply involved in their own health care on a significant scale. This strategy could be used as a model in developing countries for other community-based health programmes.

There is a growing interest at the national and international level to use the approach of ComDT for interventions against other diseases. The current momentum provides an important opportunity to integrate ivermectin treatment with other disease control activities, and to contribute to health care development for some of the poorest populations in Africa. But to ensure that this opportunity is properly exploited, there is an urgent need for good scientific evidence on the effectiveness of the ComDT process for interventions against other diseases, and for integrated disease control at the community level.

During its meeting in December 2002, the Joint Action Forum of APOC recommended that the Special Programme for Research and Training in Tropical Diseases (TDR) undertakes, in collaboration with APOC, a multi-country study on the use of ComDT for other diseases. TDR and APOC have responded positively to this request and the multi-country study has now been launched. The research protocol for the multi-country study was developed during a protocol development workshop held from 4–8 November 2002 in Limbe, Cameroon.

Because of the complexity of the issues involved, it was decided to prepare the study through a series of consultative meetings with key partners concerned with a multi-disease approach

to ComDT, in order to identify the principal research questions to be addressed in the study. An important finding of these consultations was that the attitudes towards ComDT vary widely, ranging from the very positive attitudes of those with experience of ComDT in onchocerciasis control, to doubts of experts in other disease areas who were not always convinced about the potential of the ComDT approach for the diseases they are concerned with. It became very clear that a scientific comparison of community-directed and alternative approaches for delivery of interventions against endemic diseases, including onchocerciasis, is very much needed to provide objective evidence on the advantages and disadvantages of community-directed interventions as compared to other approaches to the delivery of health interventions at the community level in Africa.

Statement of the problem

- Summarizes the purpose of the study.
- Is a paragraph rather than a single statement.
- Establishes the direction and captures the essence of the study.
- Is clear and concise.
- Incorporates general objectives and uses action words to succinctly outline the purpose of the study.
- Reflects the research design of the study.
- Leads to the research question(s).

The term “statement of the problem” may be misleading as it usually comprises a self-contained paragraph, rather than a single statement.

- Use words such as “purpose,” “intent” or “objective” to highlight the main idea of the research.
- Identify the key concepts being explored.
- Identify the research design (e.g. case study, ethnographic study, correlational, experimental).
- Identify the unit of analysis in the study (e.g. independent and dependent variables, population, classroom, organization, programme, event); data collection methodologies (e.g. surveys, interviews).

Example 1

In the 1990s, the Government of [x country] introduced an economic structural adjustment programme. This meant a reduction in financial allocations to social services and removal of subsidies and consequently a limit of the public health budget. Health sector spending over a percentage of total government spending declined from 5.3% in 1980 to 4.2% by the mid-1990s. The diminishing resource allocation to the Ministry of Health has seriously affected a variety of programmes, including malaria control. Malaria still ranks among the major health and development challenges in the country and remains one of the major five killer diseases. The 1998 statistics of the country's 57 districts, 16 showed an incidence rate higher than 100 per 1000 people (Source et al, 1998).

Despite the existence of the Medical Care Plan (MCP) in several districts in the country, districts such as y still record one of the highest incidences (885/1000) (Source, 1999). On the other hand, districts such as z located in the same agro-ecological region have managed to reduce the incidence of malaria over the past three years from 575/1000 in 1997 to 305/1000 in 1999. Out of the 57 districts in the country, both y and z are in the top eight poorest districts with a Human Development Index (HDI) of 0.47 (Source 2000). The proposed study will identify factors that have shaped success in malaria control in one district and not the other and draws lessons for

the development of effective strategies to optimise the use of limited resources in a country that is currently facing an economic crisis.

Example 2

Only 5–10% of the Chinese rural population, mostly in the richer eastern coastal areas, were still covered by Cooperative Medical Scheme (CMS) during the 1990s. In Vietnam, after the introduction of user charges in 1989, several provincial health insurance schemes were developed. In the schemes, industrial workers, constituting a minority in the population, were in principle insured on a compulsory basis, while other citizens, including farmers in the rural areas, could join on a voluntary basis. However, less than 2% of the rural target population was enrolled in the voluntary health insurance in 1999. The problem here is the low enrollment in the health insurance scheme and by extension, limited access to health care in the rural population.

How to know if the problem is worthy of research

To get an indication whether the problem identified would be an appropriate research project, ask the following questions:

- Is there a perceived difference or discrepancy between the situation that exists and the ideal or planned situation?
- Is there a clear reason for the difference or discrepancy to the problem?
- Is there more than one possible answer or solution to the problem?

Example

Review the following overview of a problem situation:

In District Y (population 145 000), sanitary conditions are poor (5% of households have toilets) and diseases connected with poor sanitation such as hepatitis, gastroenteritis and worms infestations are very common. The Department of Health has initiated a sanitary project that aims at increasing the percentage of households with toilets by 15% every year. The project provides materials and the population is expected to provide labour. Two years after the programme began less than half the target was reached.

Now review the following questions to understand how to conduct a systematic analysis of the situation and provide a rationale for the need to conduct research to arrive at answers to the problem:

- What is the discrepancy?
- What factors can explain this difference?
 - Service-related factors? Failure to inform and involve the community? Bottleneck in the supply of materials? Training and effectiveness of sanitary inspectors?
 - Population-related factors? Lack of understanding of relationship between disease and sanitation? Poverty?
 - Physical factors? Ecosystems? Hard soil? Area always flooded?

To ensure that you have identified a legitimate problem in need of research and worthy of funding, strategically situate your proposal so that it will:

1. enable researchers and stakeholders to critically evaluate existing knowledge, pool this knowledge and identify gaps that IR projects should fill;
2. clarify the problem and the possible factors that may be contributing to it;
3. facilitate decisions concerning the focus and scope of IR (relate significance to specific aims).

These three considerations will be emphasized in the introduction of your proposal and help formulate the rationale for why the research needs to be conducted. Reflecting upon these considerations is also important in helping you first think broadly in order to be able to then narrow your focus to identify research objectives within the broader context.

Narrowing the research problem

1. Clarify the viewpoints of all stakeholders.
2. Specify and describe the core problem.
3. Identify the factors that may have contributed to the problem and clarify the relationship of the problem.

By now, the research team should be able to develop an overview of the problem and – through a systematic analysis of existing resources and literature – provide a rationale for why conducting the proposed research would provide answers, solutions or alternative strategies to the identified problem. Now follow the steps below to help narrow focus and identify research objectives within the broader research problem:

1. Clarify the viewpoints of all stakeholders.
 - List all problems
 - Illustrate the discrepancy

Example: Increasing defaulter rate among TB patients

- *Poor health services management, as identified by policy-makers.*
- *Social stigma associated with TB, as identified by affected communities.*
- *Negative attitudes of health workers, as perceived by service users.*

2. Specify and describe the core problem.
 - Quantify the problem
 - Describe the problem in detail

Example: Increasing defaulter rate among TB patients

- *How widespread is the observation? Which regions are persistently affected? Are there certain areas that may be potential low compliant areas?*
- *Who is affected the most?*
- *How severe is the problem? What are the consequences? e.g. increasing morbidity, deaths, a waste of resources, development of multidrug resistance.*

3. Identify the factors that may have contributed to the problem and clarify the relationships of the problem.

Example: Increasing defaulter rate among TB patients

- *Staff who are poorly trained because there are inadequate materials on TB.*
- *Health educators who have little understanding of patient prescriptions and do not provide systematic advice and counselling to patients. This results in patients not understanding treatment requirements and a high default rate.*

Research objectives

Research objectives should be SMART (i.e. Specific, Measurable, Achievable, Realistic and Timebound). In addition, you need to consider whether the research is:

- relevant
- new or innovative
- urgent
- politically acceptable
- ethical

When writing the Research objectives, ensure that the team addresses the following questions:

Is the research realistic?

Describe the complexity of the proposed research. Are there adequate resources to do the research? Is it feasible to conduct and report the findings in 12 to 36 months?

Is the research timely?

Provide a rationale for why your research is timely, and convince readers of the urgency for research in this area in order to generate information/solutions to problems affecting a specific community.

How is the research relevant?

Describe how large or widespread the problem is, and also who is affected, who considers this a problem. Also refer to the potential for the disease/condition to spread/increase if not treated, the potential burden to the health system, and existing or potential economic impacts of the problem on the target population.

For example:

Both the Chinese and Vietnamese governments have recently recognized the problems of lack of access to health care for the rural population. New policy initiatives are being developed to address the issues. In China, the central government has taken a decision to allocate 10 yuan/year/person for all the rural population in the central and western parts of China, in order to subsidize the re-establishment of a new Cooperative Medical Scheme, while it has also asked the provincial government to provide the same amount of money to support the schemes. In Vietnam, the government has issued a decree to significantly expand coverage of voluntary health insurance schemes providing the near-poor with subsidized insurance cards. This implies that the governments of the two countries have considered direct financial support to service the demand side (particularly the poor and the near-poor) via health insurance mechanisms, although they continue to allocate certain amounts of money from the government health budget to support the formal health sector. Against this background, the proposed research is expected to support policy initiatives by the governments, by bringing together the resources of experienced researchers from China, Vietnam and three European countries to study, evaluate and draw policy lessons for the ongoing movement to strengthen access to effective healthcare by making health insurance schemes work for the most vulnerable rural population in the two countries.

Is the research new or innovative?

Point out how the research will add value by doing something new or extend/improve upon something already in existence. You need to convince readers that you are not duplicating something that has already been done.

For example:

The project will produce innovations in a number of areas through its approaches and activities as follows:

- Piloting and testing new rural health insurance arrangements including innovations in:
 - benefit packages, in particular the development of schemes including primary and outpatient health services in addition to catastrophic health care costs in China;
 - provider payment mechanisms, in particular options such as capitation for pay for outpatient services at the village and township level health services in China, and commune health stations in Vietnam;
 - organization and management, including measures to increase accountability and transparency;
 - government subsidies in both countries.
- A participatory approach to involving major stakeholders such as policy-makers and potential/ actual service users at all stages of the research in order to maximize the relevance and impact of the findings.

Is the research urgent?

Demonstrate how the research results are urgently needed by policy-makers, implementers and health care providers in order to provide evidence to create a change, implement an intervention or put a stop to current practices.

For example:

During the SARS (severe acute respiratory syndrome) outbreak of 2003–2004, implementation research regarding uptake of SARS protocols was urgent.

Is the research politically acceptable?

IR projects often address topics of high interest to local and national authorities. It is advisable to involve policy-makers in the project design to ensure political acceptability and facilitate implementation of study results.

For example:

Undertaking TB research among the prisons in some communist countries may be seen as politically unacceptable. Consulting with and involving the authorities could mitigate this.

How will the results and/or recommendations be applicable to the target community?

Explain the likelihood of adoption of recommendations resulting from the research and how the findings will be used to improve health and health care. Demonstrate that you have done your homework and are aware of resources available, as well as any additional resources needed to facilitate implementing the recommendations.

Is the research ethical?

Explain how the research will be beneficial to the members of the community being studied. How will the research findings be shared with the target group? Can informed consent be obtained from the research participants? How will you take into account the condition of the participants? Will the results be shared with those who are being studied?

For example:

In scaling-up use of GeneXpert TB diagnostic device, more multidrug-resistant tuberculosis (MDR-TB) would be detected. It would be seen as unethical if diagnosed MDR-TB cannot be treated in an appropriate way (e.g. because of lack of technical capacity).

Overall objectives

- List specific and overall objectives.
- Outline the purpose for conducting the research.
- Clearly state what the study is expected to achieve in general terms.
- Align with the broader social, economic and health concerns outlined in the overview of the introduction, and further focus the context of the research down to an essential purpose.

Different funding agencies use different terminology (objectives, goals, aims). Sometimes these terms are used interchangeably.

The term “general objectives” is sometimes used interchangeably with “purpose of the research” or “overall objectives.” The general objectives should not be unrealistic (reduce morbidity and mortality) but rather reasonable, such as provide programme managers with information useful for improving service delivery. The General objectives outline the purpose for conducting the research. The purpose section may organize the study into clearly defined phases and facilitate the development of the research methodology and data collection to gather information to address the identified problem.

The particular research project could contribute in part to the overall objectives, but cannot fully fulfil them, since they may be affected by other factors such as education, manufacturing, etc. On the other hand, the specific objectives must be completely achievable through this project. The specific objectives will be used to measure the success or failure of the project.

Example 1

To contribute towards poverty reduction and health improvement for people living in poor rural areas of developing countries; to increase equity in health by making evidence available for health policy-makers for an effective, sustainable and affordable rural healthcare financing system in China and Vietnam.

Example 2

To maximize the equity, effectiveness and efficiency of close-to-community services in rural areas and urban slums in six countries.

Specific objectives

- Specific objectives are a breakdown of general objective(s) into measurable action statements that outline what will be done, where and for what purpose.
- Use action verbs when defining specific objectives (e.g. *determine, compare, verify, calculate, describe, establish, evaluate*).

Avoid the use of vague, non-action verbs when writing your Specific objectives (e.g. appreciate, understand or study). Use verbs such as: train, supervise; distribute when describing project activities. Resist the temptation to put too many or over-ambitious specific objectives in your IR proposal that cannot be achieved. After formulating your specific objectives ask yourself the following questions: Are the specific objectives clear, defined in operational terms that can be measured, realistic, and do they demonstrate how the research results will be used to solve the research problem?

Good example

To determine progress and constraints of visceral leishmaniasis active case detection at the district level using findings from previous years as baseline.

Poor examples

- *To provide patient-focused training programmes to enhance both self-management and peer-management of diabetes as a means to develop leaders.*
- *To study the behaviours of health workers in Uganda.*
- *To develop an implementation strategy for elimination of TB for a national TB control programme in China.*

Research question(s)

- Should be of interest to the researchers, policy-makers; decision-makers, funding agencies, health care providers and the community the research will affect.
- Should be answerable.
- Are shaped by the problem and in turn shape the design of the research.
- Are clear and specific.
- Are feasible.
- Provide information required to evaluate ongoing interventions and/or progress.
- Analyse possible causes for missed targets (in order to find solutions).
- Answering the question will result in important information.

The research methodology should be designed in such a way that by conducting the research the research question(s) will be answered.

IR question(s)

- Primarily address the needs of policy-makers, programme managers and health care providers, not only.
- Describe the health situation and intervention (include those in place and potential interventions).
- Provide information required to evaluate ongoing interventions or progress needed for making adjustments in the intervention.
- Analyse possible causes for missed targets (in order to find solutions).

IR questions are identified through an analysis of the situation and evidence, not merely based on the instinct of the researcher, policy-makers, programme managers or health care providers.

An IR question does one or more of the following:

1. Describes the health situation and intervention (include both situations and interventions in place and potential interventions)
 - Magnitude of the problem
 - Distribution of health needs of the population
 - Risk factors for some problems
 - People's awareness of the problem
 - Utilization patterns of services
 - Cost-effectiveness of available and potential other interventions

2. Provides information required to evaluate ongoing interventions or progress needed for making adjustments in the intervention
 - Coverage of priority health needs
 - Coverage of target groups
 - Acceptability of the services
 - Quality of services
 - Cost-effectiveness of the intervention
 - Impact of the programme on health
3. Analyses possible causes for missed targets in order to find solutions
 - Availability
 - Acceptability
 - Affordability
 - Service delivery problems

This information is required to formulate adequate policies, adapt or plan an intervention, and assess progress and the need for adjustments.

As your team conducts its own implementation research, remember that *the question determines the methods, and the purpose determines the framework*. IR questions address the design, implementation and outcomes of programmes. IR also asks: “Are there unintended consequences?” and “Why is it happening as it is?” IR questions are driven by implementation problems and should be designed for action-oriented research in collaboration with stakeholders.

Formulating IR questions

When formulating an IR question, you should consider the following:

- How could it best be answered?
- How could it feasibly be answered?
- What data is available? What data is needed?
- What can be controlled?

Once the problem has been identified, the next step is to formulate a question addressing that problem. Your approach depends on context and availability of information. Remember that IR problems are programme embedded – *they begin and end in programmes*. So, engage programme stakeholders early to formulate IR questions. The way questions are formulated drives research methods. These are helpful sources for formulating IR questions:

- Programme progress, annual, or evaluation reports from monitoring and evaluation activities.
- Medical literature, meta-analyses, and literature reviews.
- Scientific meetings and conferences.
- New ideas from previous research or formative qualitative studies (e.g., interviews).
- Funding agencies' annual reports.
- Questions asked by programme staff and students.
- Local documents – project progress reports, theses, dissertations, seminar proceedings.
- Annual review or dissemination meetings.
- Geographic information systems (GIS) data that identify geographic location and distribution of problems.

Prioritizing IR questions

In prioritizing research questions, pay attention to:

- relevance
- avoiding duplication
- urgency of need
- political acceptability
- feasibility
- applicability of results or recommendations
- ethical acceptability

A programme may generate multiple, simultaneous implementation problems and questions. This can be overwhelming, so it is important to prioritize IR questions, ensuring efficiency and responsible practice of IR. The following seven criteria should help with prioritizing IR questions (Table 6):

Table 6. Criteria for prioritizing IR questions

Criteria	Considerations
Relevance	<ul style="list-style-type: none">• How large or widespread is the problem?• Who is affected by the problem?• How severe is the problem?• If the problem is not checked, is there potential for spread?• Who considers this a problem?• Is this problem a burden to the health system? How severe is the burden?• What is the economic impact of this problem on the population?
Avoidance of duplication	<ul style="list-style-type: none">• Has this question or problem been researched before?• Are there any interventions that have effectively addressed this problem?• If yes, are there any major questions that deserve further research?• Is my context so different that I cannot use the results of previous intervention research?
Urgency of need	<ul style="list-style-type: none">• How urgently do the policy-makers, implementers and health care providers need results?• Will timeliness impact changing course, taking on new interventions or stopping what they are doing?
Political acceptability	<ul style="list-style-type: none">• It is advisable to do study implementation problems of high interest and those that are supported by local or national authorities.• Study results for salient issues with political support are more likely to be implemented.• Politically accepted implementation problems can likely rely on involvement of the policy makers in the study.
Feasibility	<ul style="list-style-type: none">• How complex is the research?• Are there adequate resources to do the study?• Is it feasible to conduct and report the findings in 12 to 36 months?

Criteria	Considerations
Applicability of results or recommendations	<ul style="list-style-type: none"> • What is the likelihood that recommendations will be adopted? • How would the findings be used to improve health and health care? • Are there available resources for implementing the recommendations?
Ethical acceptability	<ul style="list-style-type: none"> • How acceptable is the research to those who will be studied? • Does the target group share the implementation problem? • Can informed consent be obtained from the research subjects? • Will the condition of the subjects be taken into account? • Will the results be shared with those who are being studied?

Review of literature (synthesis of existing knowledge)

- Involves library searches to find relevant and up-to-date resources, reading and synthesizing the existing information and literature into a succinct overview.
- Demonstrates relevance by establishing what is already known about the research problem and how it has been approached in the past.
- Provides a rationale for why it is crucial to conduct the research.
- Indicates what is not known about the topic.
- Helps you refine the statement of the problem.
- Provides the 'state of knowledge' on the topic and sets up the research question(s) being investigated.
- Establishes credibility.

The review of literature synthesizes the relevant and most up-to-date information on the proposed research topic and leads to setting up the research question(s) being investigated. A literature review should demonstrate that you have read the existing work in the field with insight, thereby providing the reader with a picture of the state of knowledge and of major questions in the subject area being investigated.

By providing an overview of the existing available information, you avoid duplicating existing research by finding out what research has already been done on the topic. Reviewing the existing information will help you refine your statement of the problem, analyse various approaches already used in related studies, and assist in forming convincing arguments related to your research. By reading your overview, readers should be convinced that you are familiar with the topic and you have done extensive background research in the field.

In session one 'Write-shop', you will strategically situate your research problem in the existing knowledge and literature, in order to establish a rationale for why it is important that your identified problem be researched. Writing your rationale is the first step in developing the synthesis of existing knowledge for your IR proposal.

Completing review of literature

- Reading and writing can be an iterative process and time consuming.
- You are unlikely to complete your synthesis of existing knowledge during the current training.

Our goals are to:

- ensure you understand what is involved

- ensure you are aware of tools available to assist you with this task
- provide you with examples of a brief review of literature from IR proposals

Conducting a literature review involves reviewing the existing knowledge and doing library searches to find relevant resources (i.e. research articles, research studies, reports, government documents, and white papers), reading, and then organizing and synthesizing the information into a succinct overview of the topic. You may find you need to read about the topic for several days or weeks before beginning to write. At some point, however, you need to begin to write. Often you will find that once you begin to write, the process can feel overwhelming and you need to go back and do some more reading. You need to look for major concepts, read with a purpose, be a critical reader and start to write while still reading. Reading and writing can be an iterative process. As such, developing a comprehensive synthesis of the existing information can be an extremely time-consuming and laborious task.

During this workshop you will not have time to produce your review of literature for your research topic to an extent sufficient to support your IR proposal. As indicated earlier in this workbook, it is important to at least read about the problem you have identified before attending the workshop.

We will, however, provide an overview of what synthesizing the existing information and literature means, make certain that you are aware of the tools available to assist you with this task and provide you with IR examples of syntheses of the existing knowledge and literature.

Once you are back in your communities, you can continue to collect and read articles and develop your review of literature. If you have the resources, you may even want to outsource this task to a consultant who has conducted reviews of literature before.

Characteristics of literature review

- Presents an argument based on existing information (e.g. published literature; reports, government documents etc.).
- Synthesizes information from many sources.
- Critiques research studies for methodological shortcomings (when and if appropriate).
- Synthesis should support your research question.

The review of literature is not merely an expression of the research team's opinion of an issue or topic, but instead presents an argument based on the existing information, including published literature. An effective synthesis doesn't depend on, or elaborate upon, one or two studies, but synthesizes the existing information from many sources. It should be well written with one paragraph logically flowing into the next. The review of literature does not just describe or summarize the content of an article but critiques research studies for methodological shortcomings, as appropriate.

In the past, it may have been acceptable not to provide a strong synthesis of the existing knowledge due to the research team's location and lack of access to libraries and resources. However, today anyone who has access to the Internet can find most of the existing literature. Several search engines such as Pubmed (<http://www.ncbi.nlm.nih.gov/pubmed>), Hinari (<http://www.who.int/hinari/en/>) and Google Scholar (<http://scholar.google.com>) will be helpful in this regard. You can also work with a librarian, or assign a specific member of the project team to help you find and access the information you need.

In summary, the synthesis of existing information:

- defines and limits the problem or research question(s);

- demonstrates familiarity with the topic;
- establishes credibility;
- places the research in context;
- demonstrates relevance by making connections to a body of knowledge;
- integrates and summarizes what is already known about an area;
- helps avoid duplication;
- identifies agreement and discrepancies between and among prior research;
- helps the researcher select methods and measures;
- stimulates new ideas.

Referencing

- The ideas included in the review of literature should be properly cited.
- Software programmes are available to help manage, store and use references effectively.
- Improper referencing can hamper your chances of success in your grant application.
- Not referencing or referencing improperly can result in plagiarism.
- All references cited in the proposal text should be included in the reference list.

The ideas included in the review of literature should be properly cited using the reference style required by the agency to which the proposal is being submitted (e.g., APA, MLA, Chicago, Harvard). There are various software programmes available to help manage, store and use references effectively (e.g. EndNote, Mendeley). If possible, install the 30-day trial EndNote software or the free Mendeley software onto your computer.

It is essential that you reference properly. Not adhering to the conventions of proper referencing is an indication of sloppy research and consequently will hamper your chances of being successful in your grant application. Moreover, if you do not reference properly, you run the risk of plagiarizing, which can have severe career and academic ramifications. There are programmes that can help you check against plagiarism during your write up. An example is Desktop Plagiarism Checker.

All the references cited within your proposal (and only the ones cited in your proposal) must be listed in the references section of your proposal document.

Example 1 (well referenced)

Following World War II, [Q country] had built an extensive tuberculosis control system that relied on active case-finding using mass-miniature radiography and prolonged inpatient treatment with effective anti-TB drugs (Ref., 1999). The collapse of that country left the burden of TB control on impoverished regional authorities and precipitated a disruption in case finding, diagnostic quality and clinical effectiveness. The emergence of multidrug-resistant TB (MDR-TB) in this region has followed the disruption of effective drug delivery to TB patients (Ref., 1998).

Because the international community had judged the Q country's system of TB control as being too costly, in 1994, the WHO assembled the heads of TB control programmes in this region to promote a standardized framework for TB control later known as 'DOTS' (Ref., 2001). In 1998, the Q country Government adopted the DOTS strategy and proceeded to strengthen TB services throughout the country. While a fall in the TB mortality rate has followed the availability of first-line TB drugs and smear microscopy facilities, TB control continues to suffer from at least two limitations: TB patients continue to abandon treatment at a rate of 8% or higher, and more than 5% of newly diagnosed patients have MDR-TB (Ref., 1999). Rates of TB infection have risen in z City and w district during the past decade, as in other parts of the country, and may be

associated with poverty and the deterioration of TB control and prevention systems due to a lack of resources. The incidence of other communicable diseases such as diphtheria and hepatitis has also increased (Ref., 1999).

The international literature on directly-observed therapy (DOT) suggests that successful community-based TB control programmes depends on some combination of incentives and enablers for patients and health care workers to promote treatment adherence (Ref. et al., 2000). In addition, the medical literature on MDR-TB treatment shows that short-course chemotherapy does not produce acceptable clinical outcomes for patients already resistant to isoniazid and rifampin (Ref., 2000). In settings with highly prevalent MDR-TB, effective TB control will likely require 18- to 24-month courses of individualized treatment regimens that include second-line anti-TB drugs (WHO, 2001). In response to the problems of treatment adherence and MDR-TB, the National Tuberculosis Control Programme and the State Medical University have initiated MDR-TB treatment with second-line drugs in several pilot regions, and have begun to develop an innovative programme of outpatient enhancers and enablers they have termed DOT-flexibility and follow-up (DOT-FF) (Ref., 2001).

Example 2 (poorly referenced)

Large segments of the world's rural population remain vulnerable to the full financial cost of illness. Over the past two decades a growing number of developing countries have organized community-based or rural health insurance schemes to improve access to health care for those working in the informal sector. The need to develop and organize health insurance for the rural population and informal sector workers, as well as their dependents, has been linked to two sets of failures in a number of countries:

- *Government failure to collect taxes and organize public finance, to provide social protection for vulnerable populations, and to exercise oversight of the health sector.*
- *Market failure to offer an effective exchange between supply and demand, partly due to the gap between needs, demand and ability to pay, and partly due to the prevalence of non-monetary transactions in the informal sector.*

The strengths of health insurance in mobilizing and managing health resources are seen as based on three factors: social capital (safety net formalized by family, friends and community for the low-income groups); pre-existence of some community institutions; and interconnectivity between local communities and external institutions committed to advance the general welfare of society. However, there are also many problems and challenges in developing sustainable health insurance schemes in low- and middle-income countries because of a variety of constraints, including human and financial resources.

Group activity: Statement of the problem

Now that your team has developed an overview of your research problem(s), a rationale for why the research is justified, and general and specific objectives, you are ready to draft your statement of the problem, which will logically lead you to your research questions.



In your teams, read the example statement of the problem and use it as a guide to discuss the statement of your own research problem.

Example [based on a proposal related to malaria control in two different districts in an African country]:

In the 1990s, the government of country x introduced an economic structural adjustment programme. This meant a reduction in financial allocations to social services and removal of subsidies and consequently a limit of the public health budget. Health sector spending over a percentage of total government spending declined from 5.3% in 1980 to 4.2% by the mid-1990s. The diminishing resource allocation to the ministry of health has seriously affected a variety of programmes, including malaria control. Malaria still ranks among the major health and development challenges in the country and remains one of the five major killer diseases. The 1998 statistics of the country's 57 districts showed an incidence rate higher than 100 per 1000 people in 16 districts (Source, 1998).

Despite the existence of the malaria control programme in several districts, some districts (such as y) still record one of the highest incidences (885/1000) (Source, 1999). On the other hand, districts such as z, located in the same agro-ecological region, have managed to reduce the incidence of malaria over the past three years from 575/1000 in 1997 to 305/1000 in 1999. Out of the 57 districts in the country, both y and z are in the top eight poorest districts with a Human Development Index (HDI) of 0.47 (Source, 2000). The proposed study will identify factors that have shaped success in malaria control in one district and not the other, and draws lessons for the development of effective strategies to optimize the use of limited resources in a country that is currently facing an economic crisis.

Write-shop

During the evening, work in your teams to develop the following for your team's project:

- Working title
- Statement of the problem for your IR proposal (1/2 page)
- Research question(s)
- Specific objectives for your project (4 to 6 objectives)

Be prepared to present your drafts on day 2.



Group discussion

Each group will give a 10-minute presentation to the group with their results from the previous evening's write-shop.



2. RESEARCH DESIGN

As part of this session, your research team will build capacities that allow you to determine the specific research design that will be most effective in meeting your research objectives and answer your research question(s):

- Develop a research design outlining the procedures that will be taken to collect and analyse the data.
- Identify the research method (qualitative, quantitative/or mixed) that will be most effective in attaining your research objectives and answering the research question(s).
- Describe the quality management plan that your team will put in place to ensure quality.
- Describe the participants.
- Explain the steps you will take to ensure all ethical protocols and procedures will be addressed.

The research design is a blueprint or plan delineating your research methods; the steps or procedures you will take to collect and analyse your data; research sample size and participants; and how you will address ethical considerations. The research design section of your proposal will generally include four sub-sections:

- Study participants
- Research methods
- Data collection
- Data analysis

There are also four main options of research design, with each one addressing a different fundamental need in the study setting (Table 7).

Table 7. Research design categories and the needs they address

Need	Design	Example
Adequacy	Before-after or time series	Introduction of health insurance in a resource-poor setting, and examination of the impact of health insurance on access to health care. Using before-after or time-series design to collect corresponding data for evaluation.
Plausibility	Comparison of intervention to control group (pre-post intervention) Cross-sectional studies	Introduction of a new approach to the improvement of maternal health care in selected districts. A number of districts with a similar socioeconomic development levels were selected as control sites. The impacts or effects of the new approach were assessed by a comparison of new approach/ intervention to control districts, using the method of 'differences in differences', for example.
Probability	Clusters RCT; pre-post intervention and control sites	Using mobile phones as a reminder to increase adherence to TB treatment. Each district is used as a cluster. Among ten districts, a cluster-randomized controlled trial is employed to test the impact of using mobile phones as a reminder in the five districts randomly selected. The other five districts served as control sites.

Need	Design	Example
Explanatory	Repeated measures on context and mechanisms	Using quantitative, qualitative or mixed methods to understand and examine change in use of health services by pensioners after retirement, and analyse main factors resulting in the changes.

Once the overall study design has been determined, it informs the choice of participants, research methods and data collection/analysis approaches that are used/adopted.

Study participants

The participants section should include a full description of the subjects (sample) or participants who will be involved in the research, along with how they will be selected (purposeful or random sampling) details of the sample size and participant criteria. This allows the reader to make conclusions regarding the generalizability of the study. Criteria for becoming a participant, which may include demographic information such as age and sex, should be specified, along with descriptions of characteristics that are relevant to the research (e.g. years of experience, when they were diagnosed with the disease being researched, level of education etc.).

Outline the strategies that will be taken to ensure participants feel free to express their opinions during interviews, focus group discussions and other data collection procedures. For example, are venues private? Are there power dynamics to consider so that participants do not feel intimidated or threatened to say exactly what they are feeling and thinking? For example, if interviewing a patient, they may not feel comfortable expressing their opinion in front of their physician. Or when interviewing health care staff they may not feel comfortable saying how they feel in front of their superiors or managers. Consider how your IR proposal can outline appropriate procedures to ensure that participants feel comfortable and confident to provide honest, reliable responses.

The exact structure of the study participant section of your proposal will also be influenced by the selected research methods.

Example of Participants section of an IR proposal

For the key informant interviews for a study on TB in the prison system of country X, a comprehensive list of officials to be interviewed will be developed based on the stakeholder analysis and on consultations with the national TB control programme (NTBCP) personnel. A preliminary list of officials has been compiled and includes the following:

- Minister of health (or his deputy)
- Deputy of the ministry of health responsible for epidemiology and infection control
- Director of the NTBCP
- Chair of the sanitation and epidemiological services committee
- Ministry of justice
- Deputy of the ministry of justice responsible for the prison system
- Chief medical doctor that oversees the prison system
- Ministry of internal affairs
- Deputy responsible for detention centres

- Chief TB medical doctor (detention centres)
- Ministry of social security (head administrator)
- Ministry of finance (head of budgeting department)
- Head of regional political authority
- Head of health department of that authority

Group activity: Study participants

In your research teams discuss who you think your research population will be. Will you have one site or multiple sites? Why will you choose the site(s) you choose? Discuss who you think your participants will be in the study. How many participants will you need? What will be the criteria for becoming a participant?

Will you need a variety of participants in order to get different perspectives on an issue (patients, physicians, family members, members of the community)? Will you have a control group of participants? Do you need to choose a representative population for certain aspects of data collection? For example if you are conducting individual interviews do you want your participants to vary in (age, gender, education, experience etc.) in order represent the sample population?

Draft an outline of your participant section. You will need a general section describing your participant population. You will also need to estimate how many participants you will want from this population for each data collection method (surveys, focus group discussion, interviews etc.).



Research methods

There are three general types of research methods qualitative, quantitative or a combination of both (mixed methods), depending on the purpose of the design. Quantitative methods are better for answering the question: What is happening? Qualitative methods are suited for answering the question: Why is it happening?

Qualitative methods

Qualitative research is generally used to explore values, attitudes, opinions, feelings and behaviours of individuals and understand how these affect the individuals in question. It may also be used to help explain the results of a previous quantitative study.

Qualitative researchers are concerned with individuals' perceptions of specific topics, issues, or situations and the meanings they assign to their lives. This kind of research is important for theory generation, policy development, improving educational practice, justifying change or a particular practice, and illuminating social issues. Qualitative research uses data collection methodologies such as interviewing, observation, and documents (e.g. diaries, historical documents). The results are descriptive or explanatory rather than predictive.

For qualitative approaches, your proposal will need to outline the following sections:

- Rationale
- Data collection
- Data analysis
- Trustworthiness
- Participants
- Rationale

If your research team decides to use qualitative methods in your study, your proposal should describe why qualitative approaches were chosen (explain how qualitative methods will provide information that will help you address your research objectives and research questions).

For example, qualitative research may be appropriate because in your research you want to explore values and behaviours of individuals, and to understand how these affect the phenomena in question. Qualitative methods may also be appropriate because it will help further understanding of the results of a previous quantitative study.

Qualitative methods may be used because the study aims to generate theory, develop policy, improve health care practice, justify change of a particular practice, or illuminate social issues. Other reasons for using qualitative methods could be to provide context, a deeper understanding of stakeholder's need, rich data and participants' perspectives.

Qualitative data collection

When collecting qualitative data it is preferable to gather data using more than one data collection method. Obtaining information on the same phenomena in a variety of ways allows the researcher to 'triangulate' (or cross-check/verify) the data, which adds rigor to the research. The data collection process in qualitative research is emergent. The design is flexible to allow the researcher to investigate themes (findings) in more detail as they emerge.

Qualitative methods use data collection methodologies such as interviewing, observation, discussions and review of documents (e.g. diaries, historical documents). The results of qualitative research are descriptive or explanatory rather than predictive, and are typically time-consuming to collect.

In your IR proposal, indicate which data collection methods you intend to use and why. The following table may be helpful to you in this process. It provides an overview of qualitative data collection strategies (Table 8).

Table 8. Qualitative data collection strategies

Strategy	Summary and examples
Participant observation	<p>Researcher participates to some degree in the natural setting over an extended period of time: Systematic observation of verbal and non-verbal actual behaviour in which trained observers use a structured recording form. Data are collected by observing, interviewing, note taking and/or journaling. Researcher develops a relationship with the participants, which may affect the data collected.</p> <p><i>Proposal example:</i></p> <p><i>Semi-structured direct observation will be carried out in selected facilities to assess and compare the behaviour of health staff towards patients who are/not members of the revised schemes in at least two facilities in each study county, such as one township or commune health centre and one county or district general hospital.</i></p>
Non-participant observation	<p>The researcher does not participate in any activity in the natural setting. Data are collected by observing, note-taking and/or journaling. Researcher does not develop a relationship with the participants and therefore cannot explore further issues in relation to observations made unless this approach is complemented with a follow up.</p>

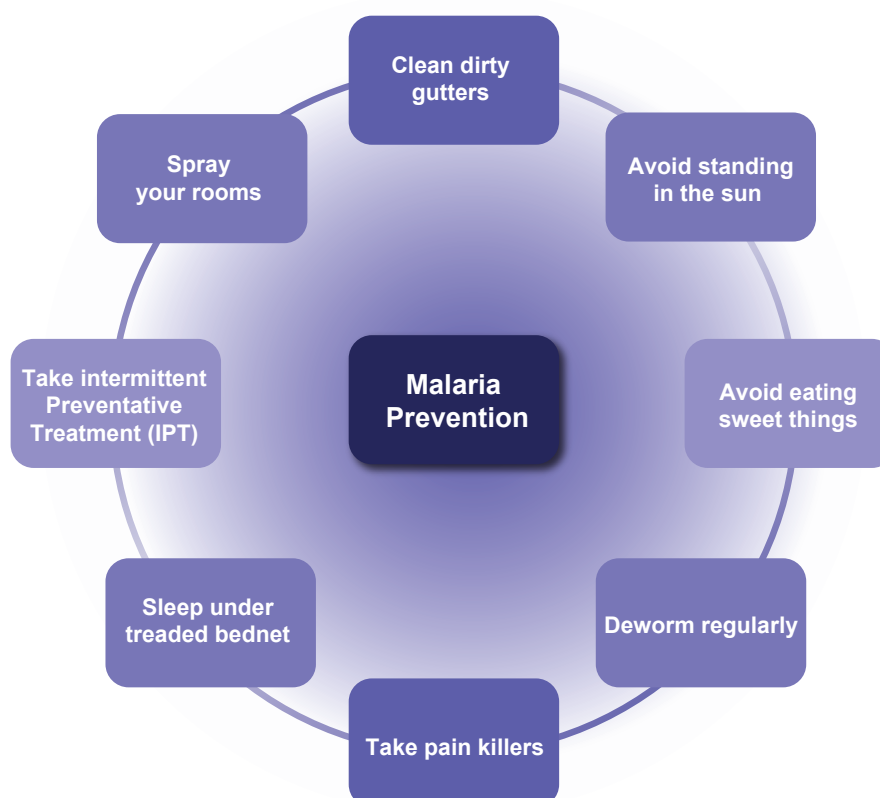
Strategy	Summary and examples
Field observation during a transect walk	Detailed descriptions of events, actions, behaviours, people and objects in a natural setting. Field observations are written in the form of field notes.
In-depth interviews	<p>A purposeful conversation directed to the participant by the researcher. The researcher will typically develop an interview guide beforehand. The researcher encourages the participant to talk in-depth, prompting more detail whenever possible without leading the participant to specific answers. Interviews are often recorded and transcribed. The average length of an interview is one hour (or less).</p> <p><i>Proposal example:</i></p> <p><i>It will include in-depth individual interviews with: people suffering from 'catastrophic illnesses'; including both members and non-members of revised schemes and those who have used and not used services; health policy-makers at national and local levels; and rural health insurance scheme managers.</i></p>
Review of documents and artefacts	<p>Records of past events that are written or printed (e.g. letters, anecdotal notes, diaries).</p> <p>Material objects and symbols of a current or past event, groups, organization, or person that reveal social processes, meaning, and value (e.g. diplomas, awards, papers, logos etc.).</p>
Video/film/ photographs	Media that capture the daily life of an individual, group or event under study. Can be viewed repeatedly to record behaviours.
Focus group discussion	<p>A 1–2 hour discussion, guided by a trained moderator in which 6 to 10 similar respondents (age, gender, social status) focus on a list of defined topics. The discussion, designed to reveal beliefs, opinions and motives, should take place in an informal setting. Data collection may be enhanced by the interaction between and among participants.</p> <p><i>Proposal example:</i></p> <p><i>This will comprise of focus group discussions using participatory techniques with: members and non-members of the revised schemes (including different age, gender and socioeconomic groups); and health service providers at county/ district levels and below, including general practitioners/ primary care providers, preventive service providers, and out-patient and in-patient providers</i></p>

Plan for qualitative data analysis

Qualitative data analysis consists of data management, data reduction and coding of data. In short, the goal is to identify patterns (themes) in the data and links between them. There is no set formula for analysing qualitative data, but the following steps are commonly used in many qualitative research studies and may be helpful to include in your IR proposal:

1. All interviews and discussions are recorded.
2. All recordings have to be transcribed verbatim (i.e. typed out in full, word-for-word).
3. All background information about the participants should be appended to each transcript.
4. In the initial step of the analysis, the researcher will read/re-read the first set of data and write notes, comments and observations in the margin, with regard to interesting data that is relevant to answering the research question(s).

5. While reading the data, the researchers begin developing a preliminary list of emergent categories into which they will group the notes and comments. These categories are guided by the purpose of the study, the researchers' knowledge and orientation, and the meanings made explicit by the participants (1). A list of these categories is compiled and attached to the data.
6. The next set of data collected is then carefully read and, with the previously constructed list of categories in mind, notes, comments and observations are once again recorded in the margin. This second data set are then grouped into categories and a list of the categories compiled. The two lists are then compared and merged to create a master list of categories. This list reflects the recurring regularities or patterns in the study.
7. These categories are then given names. Category names may emerge from the researcher, from the participants or from the literature. According to Merriam (1), these categories should be: exhaustive; mutually exclusive; sensitive to what is in the data; conceptually congruent; and, in effect, the answers to the research questions. Category names or codes in data analysis can also be derived from the questions asked in the data collection tools based on the objectives of the study.
8. Once the researchers are satisfied with the categories, the data is assigned to these categories. Taking a clean copy of the data, the researcher organizes the data into meaning units and assigns them to the relevant categories, writing the category code in the margin.
9. The researchers then create separate files for each category and cut and paste the meaning units into the relevant category, creating a file containing all the relevant data. Care should be taken to avoid context stripping by carefully cross-referencing all units and coding them with the participant's pseudonym, the date of data collection, and the page number (2).
10. The researchers then try to link the categories in a meaningful way. Diagrams can be used to facilitate this process. For example, in a study to determine causes of malaria:



11. Researchers can also use several different computer qualitative data analysis (QDA) software to help them manage their data. The term “QDA software” is slightly misleading because the software does not actually analyse the data, but organizes it to make it easier to find and identify themes. Software can also be expensive (up to around US\$900 per single user). For these reasons, some researchers prefer analysing data by hand. However, as the software improves, researchers are finding QDA increasingly useful in helping analyse data and save time. Here are some of the more common QDA software names:

- AtlasTi (<http://www.atlasti.com>)
- MAXQDA (<http://www.maxqda.com>)
- QSR NVivo (<http://www.qsrinternational.com>) previously called Nud*ist 6)
- EZ-TEXT 3.06C (<http://www.cdc.gov/hiv/topics/surveillance/resources/software/ez-text/index.htm>)

Examples: Qualitative data analysis descriptions

1. *Transcripts from key informant interviews and group interviews will be coded and analysed according to emerging themes using Ethnograph software for qualitative analysis. Data will be reported in the form of narratives or frequency tables in addition to standard thick ethnographic descriptions.*
2. *Coding of focus group interviews, ethnographic field notes and interviews with health workers using Atlas-Ti software will allow analysis of emerging themes and presentation of data in the form of narratives or frequency tables.*
3. *Transcripts from life histories will be coded and analysed according to emerging themes (Ethnograph or Atlas-Ti software). Data will be reported in the form of narratives or frequency tables. In addition, videotaped recordings of patients will be used for national and international advocacy with the permission of interview subjects. Semi-structured, open-ended interviews from patients and family members of patients will be coded and reported as narratives or frequencies of coded responses to better understand the impact of the persistence of MDR-TB in this setting.*

Trustworthiness

IR proposals should stipulate how the research team will ensure scientific rigour in qualitative methods. For example, will your study provide participants with a copy of their interview transcripts to provide them an opportunity to verify and clarify their points of view? Will you use software to help manage your data and increase rigour? Will you conduct member checks (have more than one researcher analyse sections of the data to compare and verify results)? Will you triangulate the data to increase the rigour? Will you report disconfirming evidence?

Participants

As mentioned above, ensure that numbers of participants, recruitment and selection criteria align with your qualitative methods. You may also have to consider some specific issues: Will you use purposeful sampling? What are the demographics relevant to the study, and characteristics related to the disease of interest.

Quantitative methods

The three most common designs associated with quantitative methods are: quasi-experimental, correlational, and monitoring evaluation.

Quasi-experimental research

Experimental research is the only type of research that can establish cause and effect. Furthermore, it is the only type of research where the researcher attempts to manipulate a particular variable. In experimental research, the researcher is interested in the effect of an independent variable (also known as the experimental or treatment variable) on one or more dependent variables (also known as the criterion or outcome variables). The researcher manipulates the independent variable and measures the dependent variable(s). There are usually two groups of subjects in experimental research: the experimental group, which receives a treatment of some sort (e.g. taught by a new teaching method, or receives a new drug) and the control group, which receives no treatment (e.g. continues to be taught by the old method, or receives a placebo). Sometimes, a comparison group will also be used as well as, or instead of, a control group. The comparison group receives a different treatment from the experimental group. The control and/or comparison groups are critical in experimental research as they allow the researcher to determine whether the treatment had an effect or whether one treatment was more effective than another. When possible, the subjects should be randomly assigned to the treatment and control groups.

Correlational research

In correlational research, researchers seek to determine relationships between two (or more) variables without trying to influence those variables. The degree to which the variables are related is described by a correlation coefficient, which can take any value from -1 to 1 . A positive correlation means that high scores on one variable relate to high scores on the other variable or low scores on one variable relate to low scores on the other variable (i.e. a positive correlation). Conversely, a negative correlation means that high scores on one variable relate to low scores on the other. A correlation coefficient of zero means that there is no relationship between the variables. Contrary to experimental research, correlational research does not establish cause and effect.

Not only do researchers use correlational research to describe relationships between variables, but also for prediction. If a strong enough relationship (positive or negative) exists between two variables it is possible to predict a subject's score on one variable (criterion variable) using their score on the other variable (predictor variable).

Monitoring and evaluation research

One main objective of monitoring and evaluation (M&E) research is to track implementation progress against the original design, identifying potential weaknesses, testing initial assumptions and adjusting the implementation process if those assumptions fail to hold true. Data collection activities should be carefully justified as addressing the research objective(s). Otherwise there is a risk of wasting scarce resources on data that will never be used.

One main source of data can come from the routine health information reporting systems, which often exist in low- and middle-income countries. Community health centres, district and regional hospitals, and other health facilities are usually required to submit their monthly or quarterly reports to local and national health authorities. The information often includes disease patterns, service use and expenditure, and other relevant information.

While the data from the routine health information reporting systems can be easily available and collected, the quality of the data may not be reliable, as there has been a tendency of underreporting health problems or service usages, etc. Therefore, special surveys or regular record monitoring arrangements may have to be carried out to collect data required to achieve this objective. These data collection methods include household health interview surveys, health facility surveys (e.g. hospitals, health centres, etc.), and patient surveys. When using these methods for data collection,

researchers need to develop instruments and tools, e.g. questionnaires, checklists, and organize visits to selected households and health facilities.

In your IR proposal, you should indicate who will be expected to undertake the data collection and whether training will be provided before carrying out the tasks. Appropriate supervision during the process of data collection is also required.

For quantitative approaches, your proposal will need to outline the following sections:

- A rationale
- Data collection
- Data analysis
- Reliability and validity
- Participants

Rationale

If your research team decides to use quantitative methods in your study, your proposal should describe why quantitative methods are being used (i.e. explain how quantitative methods will provide information that will help you address your research objectives and research questions).

For example, quantitative methods may be appropriate because in your research you want to illustrate the cause and effect of the issue or situation being investigated. You may also justify using quantitative methods in order to determine the relationship between variables in a population or explore differences between two groups (e.g. pre-post intervention; different populations).

Quantitative data collection

Quantitative methods involve the collection and analysis of objective data, often in numerical form. The research design is determined prior to the start of data collection and is not flexible. The research process, interventions and data collection tools (e.g. questionnaires) are standardized to minimize or control possible bias.

In your proposal, explain where the data will come from – health centre, district hospital, region (hierarchies for quarterly reports); how surveys will be delivered; who is facilitating delivery; how you will ensure anonymity; time required to complete survey; length of survey; number of questions on survey; sample size; how the survey will be designed; is the survey validated, etc.

The data collection tools used (e.g. questionnaire) may be one developed by the researcher or, more preferably, one that has been previously developed. Developing an appropriate and effective instrument takes a lot of time and effort and often requires special skills. If you are developing the tool, specify if you will conduct a pilot.

In your IR proposal, indicate what data collection methods you intend to use and why. The following table (Table 9) provides an overview of quantitative data collection strategies and may be helpful to this process.

Table 9. Overview of quantitative data collection strategies

Strategy	Summary
Structured observation	The researcher directly observes (watches and listens to) some phenomenon and then systematically records the resulting observations. The researcher pre-determines specific categories of behaviours that will be observed.
Questionnaire	<p>In a questionnaire, the subjects are required to respond to questions in writing or, more commonly, by marking an answer sheet. In the latter type of questionnaire, response options are often closed lists of responses in the form of yes/no/maybe; strongly disagree/disagree/undecided/agree/strongly agree; Never/rarely/sometimes/often/frequently etc.</p> <p><i>Proposal example:</i></p> <p><i>Quantitative data will be collected through the use of structured questionnaires. A standardized form will be developed at baseline and will include the following categories: 1) socio-demographic characteristics; 2) economic status; 3) medical and treatment history related to tuberculosis; 4) current health status, including but not limited to assessment of symptoms, smear, culture, weight and height (for calculation of BMI); 5) history of imprisonment or substance abuse; 6) psychosocial status; and 7) knowledge of TB.</i></p>
Performance-based instruments	Performance-based instruments are alternative forms of assessment used to demonstrate a skill or proficiency by having the participant create, produce or do something (e.g. write a paper, create a portfolio, do an athletic performance). Although popular in recent years, use of these approaches is fraught with technical difficulties. They are often time-consuming and require equipment or other resources that are not readily available.

Source: Adapted from McMillian & Schymacher (3) and Fraenkel & Wallen, (4)

Plan for quantitative data analysis

It is important to outline a plan for data management and analysis. The methods and models of data analysis should be in accordance with the proposed objectives and types of variables.

Quantitative data analysis will involve summarizing the results by calculating frequency and descriptive statistics such as means and standard deviations, and scale alphas for the participants' responses on the questionnaire items. You should explain how basic descriptive statistics such as means and standard deviations will be calculated from data collected.

The tests that you intend to conduct on the data should be explained (e.g. t-tests; hierarchical multiple regression). Specify if you intend to control variables. Indicate if any software will be used in your data analysis).

Outline as many of the following that relate to your study:

- Demonstrate appropriate analysis procedures.
- Provide a general plan for data analysis and justify its technical and theoretical soundness.
- Describe what information is needed to complete the analysis, the potential sources for this information and the instruments that will be used for its collection.
- Provide sufficient detail to demonstrate the technical soundness of all data collection instruments and procedures.
- Identify and justify procedures for analysis, reporting and utilization.

- Identify any anticipated constraints on the analysis.
- Discuss who will be responsible for analysis, and the roles of the consultants or external personnel.

Examples: Quantitative data analysis descriptions

Example 1. *Patients will be assigned a unique identifier that can be linked with outcome data collected on a quarterly basis. This standardized form will include information on: a) smear and culture conversion; b) current health status, including data on treatment outcome (e.g. cure, abandonment, failure, death); and c) psychosocial status. Some variables on socioeconomic status will also be included in the quarterly assessment form in order to assess changes over time.*

In addition to the quarterly assessment, drug susceptibility testing will be performed every six months. A separate form will be developed for these results and will be linked using the same unique identifier with information collected at baseline and on a quarterly basis.

Three databases will be constructed in Epi2000 for the intake, quarterly and laboratory forms. Prior to data entry, forms will be reviewed for random and systematic error and possible corrections will be made in consultation with the interviewers. Data entry clerks will be given a structured training that also enables them to identify problems with data quality prior to the entry of the forms into the database(s).

Subsequent to entry, the databases will be reviewed closely during the first few weeks of entry to ensure that the data are being entered and stored correctly. After this initial intensive phase, the data will be reviewed on a quarterly basis for systematic errors, blank fields, and other problems. Feedback will be provided to data entry clerks and to interviewers on a monthly basis to reduce the likelihood of systematic and random error.

Example 2. *Descriptive statistics will be generated from the structured questionnaires that will be administered with service providers. Frequencies, means and standard deviations will be calculated where appropriate for a number of health provider variables, including sociodemographic variables (such as gender, age, household size, etc.), socioeconomic status, job satisfaction, relationships with clients, and barriers to providing follow-up care.*

Example 3. *For the cohort study, descriptive statistics will be generated for baseline characteristics of the patients who are enrolled in both retrospective and prospective cohorts. Differences in sociodemographic characteristics will be noted for subsequent multivariate analyses. A description of clinical status and medical history, among other factors collected at baseline, will also be provided for both cohorts by generating frequencies, means, standard deviations and medians, where appropriate. In terms of examining time to smear and culture conversion for both cohorts, Kaplan-Meier survival curves will be constructed. In order to account for confounding variables in the analysis, Cox proportional hazards models will be employed. Linear regression will be used to examine DST outcomes based on number of drugs the patient is resistant to at follow up. Logistic regression will be used for the assessment of binary outcomes, such as treatment outcome (poor versus good), low body mass index, radiographic findings, and occupational status. Poor outcome will be defined as treatment failure, default or death. Interim outcome analysis will be done at the end of year 1 and the final analysis will be performed at the end of the 2-year follow-up period.*

Biosocial factors related to MDR-TB will also be presented descriptively. In order to examine the association of biosocial factors with MDR-TB emergence, linear regression will be employed

using the increase in the number of drugs that the patient is resistant to at follow up as the outcome. In terms of persistence of MDR-TB, biosocial factors will be associated with poor treatment outcomes using logistic regression. Confounding variables will be controlled by using multiple regression analysis.

Reliability and validity

When evaluating a data collection tool for use, it is important to consider its psychometric properties; that is, its reliability and validity. A tool is considered to be valid if it measures what it purports to measure. It is always valid for something specific (e.g. assessing attitude to care); a survey cannot be valid in general.

Ideally, any tool used to collect data should have demonstrated validity and reliability for the target population. However, researchers often need to tailor a standardized tool to make it applicable to their research. Adding questions, or amending existing ones, may negatively affect the psychometric properties of the instrument though and so is discouraged.

Your proposal should stipulate how your research team will ensure scientific rigour in your quantitative methods. It is important to explain the validity (i.e. how you will be able to draw meaningful inferences from a population) and reliability (i.e. control for stability of instrument scores over time) of the quantitative data.

For example, indicate whether the instruments you are using are standardized and whether they have been shown in previous studies and reports to have strong reliability and validity (with respect to content, criterion, and construct).

How have you indicated you will ensure scientific rigour (control group, placebo etc.)?

Participants

Include a section called 'Participants' and ensure that your sample size, recruitment and selection criteria align with your quantitative methods. Will you use a random sample? Indicate whether variables are dependent or independent. Describe the study population; selection criteria; provide demographics relative to the study (age, gender, ethnicity, income bracket, etc.) characteristics related to the disease of interest, etc.

Mixed methods

The majority of proposals use mixed methods in which qualitative and quantitative approaches are combined. Under many circumstances, a mixed methods approach can provide a better understanding of the problem than either a quantitative or qualitative research approach. Nevertheless, one of the main challenges may be to create the optimal combination (and sequence) of the two approaches.

The four most common types of mixed methods research design are: sequential explanatory; sequential exploratory; concurrent triangulation; and concurrent embedded (Table 10).

Table 10. Main mixed methods research approaches

Design type	Description
Sequential explanatory	Collection and analysis of quantitative data in the first phase is followed by the collection and analysis of qualitative data that builds on the results of the first phase. Weight is typically given to the quantitative data. Mixing of the data occurs when the initial quantitative results are used to inform the secondary qualitative data collection. It can be especially useful when unexpected results arise from a quantitative study. The straightforward nature of the design is its strength and so it is easy to implement. The main weakness of the design is the time required to implement since it falls into two phases.
Sequential exploratory	Collection and analysis of qualitative data in the first phase is followed by the collection and analysis of quantitative data that builds on the results of the first phase. Weight is typically given to the qualitative data. This design tends to be used when the primary purpose is to explore a phenomenon (e.g. testing elements of an emergent theory or determining the distribution of a phenomenon in a given population). It is easy to implement but requires substantial time for data collection.
Concurrent triangulation	Quantitative and qualitative data are collected simultaneously and then the two datasets are compared to see if there is convergence, differences, or some combination of the two. Ideally, the weight given to the quantitative and qualitative findings is equal but in reality more weight may be given to one methodology over another. Concurrent triangulation is one of the most popular types of mixed methods design. It can, however, be difficult to compare results, particularly if discrepancies arise. It also requires great effort and expertise on the part of the researcher to adequately study a phenomenon using two methods.
Concurrent embedded	Quantitative and qualitative data are collected simultaneously but there is a primary method that guides the approach. Either quantitative or qualitative data will be used to provide a supportive or supplementary role based on the primary data type. The researcher is able to collect two types of data during a single research phase. Often an embedded design is used to answer different research questions with a study.

Since mixed-methods use both qualitative and quantitative methods, mixed method proposals should include:

- Rationale (describing type of mixed methods being used)
- Data collection
- Data analysis
- Reliability and validity
- Trustworthiness
- Participants

Rationale

If your research team decides to use mixed methods in your study, your proposal should describe why (explain how using qualitative and quantitative methods will provide information that helps you to address your research objectives and research questions).

For example, using a mixed methods approach may be appropriate because you want to provide a better understanding of the problem than either a quantitative or qualitative research approach could achieve alone. Your explanation may state that you want to create a design that provides the

optimal combination and sequence of both approaches. Additional justifications for using a mixed methods approach may be because your project is interdisciplinary involving team members with diverse views or your project will be dealing with complex problems that will benefit from blending qualitative and quantitative data.

Mixed methods data collection and analysis

There are several elements related to mixed methods research that researchers need to consider for research design:

- *Timing*: Will quantitative and qualitative methods be used simultaneously (concurrent designs) or in two distinct phases (sequential designs)?
- *Weighting*: How much emphasis will be put on the quantitative or qualitative methods? Will they be weighted equally?
- *Mixing*: Data analysis needs to be matched to the design of the study. For example, in a concurrent design, one way of mixing the data is to provide a discussion about the emerging themes from the data and how they support or refute the statistical analysis. Another approach could be to combine the qualitative and quantitative data to arrive at new variables or new themes (5). In a sequential design, for example, a researcher might collect and analyse quantitative data in the first phase of the study and may then select some extreme cases to follow-up in a qualitative phase.
- *Visual diagrams*: An important mixed methods tool that incorporates a notation system and a flow chart of the research process.

In your proposal, indicate what data collection strategies and tools you intend to use and why. Use the information outlined in both the qualitative and quantitative sections (above) according to which data collection method you are explaining (for example, if using a focus group discussion, refer to the qualitative methods section – when explaining how you will use a questionnaire, refer to the quantitative methods section).

In your proposal it is important that you outline a plan of data management and analysis. The methods and models of data analysis should be in accordance with the proposed objectives and research questions.

Trustworthiness, validity and reliability

In a mixed methods IR proposal, showing how scientific rigour will be ensured throughout your study is critical. It is important to examine the validity (i.e. being able to draw meaningful inferences from a population) and reliability (i.e. stability of instrument scores over time) of the quantitative data.

To ensure qualitative validation, the researcher will use a number of strategies. First, opportunity will be provided for the participants to review the findings and then provide feedback as to whether the findings are an accurate reflection of their experience. Second, triangulation of the data will be used from various sources (transcripts and individual interviews) and from multiple participants. Finally, any ‘disconfirming’ evidence will be reported. This is to ensure that accounts provided by the participants are trustworthy.

Refer to the trustworthiness section of qualitative methods and the validity and reliability section of quantitative methods for more detailed information.

Group activity: Research design

In your research teams discuss which research design will work best for your project. Which methods will you use to collect your data? Use the examples below to help you create a table containing your research objective(s) and research question(s) and identify which data source(s) will be used to collect the data to meet the objectives of the research and answer your research questions.



Example

(1) *For the first objective, the study will analyse qualitative interviews, public discourse from newspapers and decrees, and objective measures of commitment to tuberculosis control in X city. Fifteen key informant interviews and several consensus panel discussions will be used to generate information on national and local policy processes and the translation of national and international guidelines to the behaviour of local health and social security systems in relation to MDR-TB control and ambulatory case-management. This stakeholder analysis will entail interviews with officials at four levels of government: national, region, district and city.*

(2) *For the second objective, the study will employ (a) focus group discussions with health care providers structured by occupation (e.g. nurse, physician); (b) ethnographic assessments carried out by researchers/clinicians trained in ethnographic methods; and (c) structured and open-ended interviews with health care providers responsible for TB control at the district and city levels.*

(3) *Methods for the third objective will include collection of qualitative and quantitative social data, as well as data on clinical and microbiological outcomes as part of a cohort study of patients and providers receiving a package of enablers and incentives termed DOT-FF.*

(4) *For the fourth objective, the study will compare bacteriological and clinical data with quantitative and qualitative social data collected from patients and family members in order to identify biosocial determinants and effects of MDR-TB emergence and persistence. The study will obtain the life histories of patients with MDR-TB and TB on video, if possible. Semi-structured, open-ended interviews will be conducted with patients and family members of patients to better understand the impact of the persistence of MDR-TB in this setting. In addition, the quantitative methods from M3 will help elucidate the biosocial factors potentially related to MDR-TB emergence and persistence (e.g. education, socioeconomic status, lack of social support, sideeffects from second-line anti-tuberculosis drugs as well as HIV and other co-morbidities, such as substance use.)*

Write-shop

During the evening, work in your teams to develop the following for your team's project:

- Research design
- Research methods including:
 - step-by-step procedures for your data collection
 - data analysis



- trustworthiness, validity, reliability
- participants

Be prepared to present your drafts on day 2.

Group discussion

Each group will give a 10-minute presentation to the group with their results from the previous evening's write-shop.



Quality management

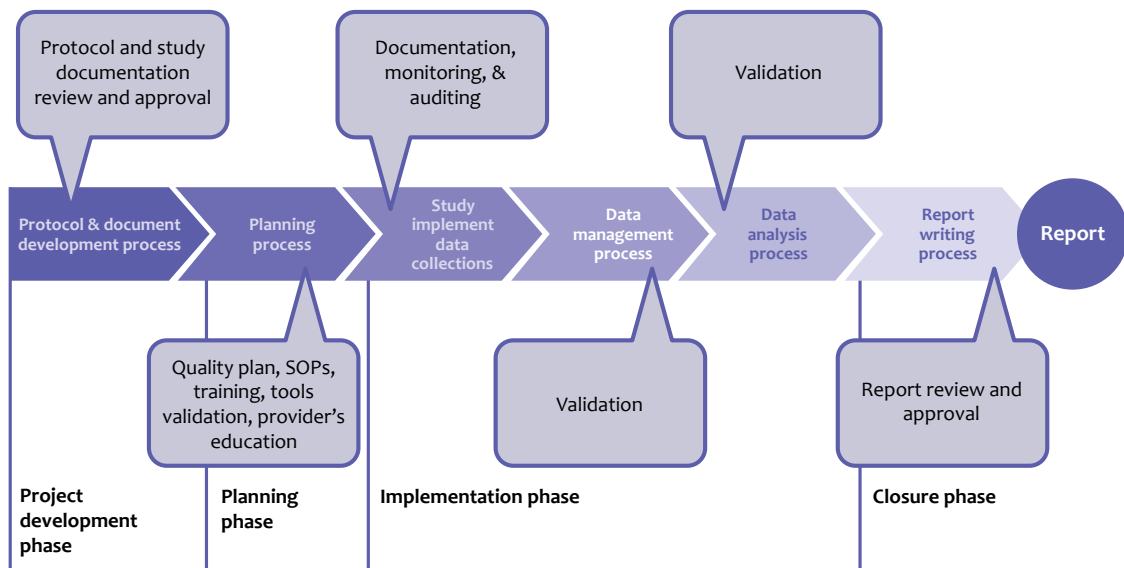
Embedding quality management into your proposal is not an optional step. Quality management is essential to ensuring that research meets or exceeds scientific, ethical and regulatory standards. Quality systems, control and assurance is integral to all research activities. Everyone engaged in the project carries the responsibility of ensuring quality. Quality management should be planned and adhered to in the research design.

In your proposal, outline exactly how you will demonstrate that your research team will take consistent, ongoing measures to monitor and evaluate quality and rigour of the research. Indicate how you will evaluate quality at various stages. How will you demonstrate that you will conduct due diligence at all data collection and data analysis steps?

If your project lasts more than one year, you may want to stipulate that you intend to have annual quality monitoring evaluations and reports. Discuss a communication plan with all stakeholders to inform them of quality standard procedures to facilitate rapid adjustments and corrections.

Quality management should also express a constant and consistent concern for research participants. How will you protect their privacy? What measures will you take to protect them from harm (e.g. train staff, adhere to ethical standards in the research ethics application etc.)?

Activities to address quality issues



The diagram provides a visual example of how you could plan and ensure continuous and consistent quality management strategies in an IR study.

Quality management activities

Some of the activities you can integrate into your IR proposal to help manage quality include:

- protocol review and approval
- standard operating procedures
- validation of research instruments
- project team training
- quality control and monitoring
- evaluation of services provided
- evaluation of the performance of service providers
- review of reports

There are many strategies that can be incorporated into your IR proposal to begin the quality standard monitoring process. Monitoring and evaluation strategies that can be implemented to facilitate the quality of your research project include:

- Information log: keep track of feedback from stakeholders, news stories published and articles written, and the number of times research has been cited in the academic literature.
- A survey: this can be conducted with stakeholders from the target audiences in order to generate feedback. For example, questionnaires can be sent via email six months and one year after a dissemination event or clients attending a family planning clinic can be asked to complete a survey regarding improvements in the quality of care.
- A series of key informant interviews with stakeholders at various levels of the health system can provide insight into whether, and how, research was used.

Use the table below (Table 11) to get additional ideas about how you can incorporate quality management into your research proposal.

Table 11. Descriptions of various quality management strategies

Strategy	Description
Protocol review and approval	Research rigour includes stipulating how you will protect the rights and welfare of research participants. Protocols may also be established to ensure consistency and diligence in data and collection procedures (standardized instruments, consistent interview protocols); checklists and established protocols to ensure consistency and rigour of data analysis across sites and among researchers.
Standard operating procedures	A project manager must establish protocol to establish rigour and consistency between and among researchers and research sites. This may include standardizing research collection procedures (establishing a protocol or checklist); creating standardized instruments and interview protocols to be used across sites and among all researchers; constant checks to ensure procedures are diligently adhered to; and holding training sessions with researchers and research assistants.
Validation of research instruments	Indicate whether research instruments are standardized and whether they have been shown in previous studies and reports to have strong reliability and validity (with respect to content, criteria and construction).
Project team training	<p>Adequate training and appropriate infrastructure are essential to patient safety, protocol implementation, and quality assurance and improvement – especially in interventional clinical trials.</p> <p>Training of researchers and assistants in data collection procedures to ensure safety of the participants, as well as to ensure consistency and research rigour between and across sites, is essential.</p>
Quality control and monitoring	Quality control is important to ensure reliable and consistent findings. What procedures will be incorporated into the research design to ensure consistent data collection methods are implemented between and among research sites and among different researchers? The proposed methodology should help investigators identify data quality problems that can be corrected while data are still being collected, and also to identify biases in data collection that might be adjusted for later.
Evaluation of services provided	<p>Monitoring and evaluating service provision is essential for analysing and, if possible, improving the effectiveness of service regimes. Establish 'critical limits' to measure the effectiveness and quality of the services provided to participants/clients/patients.</p> <p>Establish appropriate record-keeping and documentation systems. Make regular site visits to monitor progress and assess impact. Establish corrective actions. Evaluate, with relevant health care workers, achievements made and lessons learnt, and apply any lessons learnt to existing and new arrangements.</p>
Evaluation of the performance of service providers	Generating and using information on the performance of service providers can lead to substantial enhancement of transparency and accountability, which in turn fosters adherence to higher quality standards in service delivery. Assessment tools rely on external experts measuring quality and performance against a pre-determined set of indicators. Participatory monitoring and evaluation tools seek to engage service users beyond the provision of feedback, to also take an active role in the planning and implementation of the assessment. This helps to build the capacity of the local community to analyse, reflect and take action. Community scorecards envisage active involvement of the group and allow participants themselves to identify indicators of quality and performance.
Review of reports	Reports should be drafted and shared in sufficient time to provide an opportunity for all researchers and appropriate stakeholders to have the opportunity to read, react to, provide feedback on, edit, revise, and provide input into the report.

Research ethics

Any research study that collects data from or involving human subjects must undergo an ethics review. You must stipulate that you intend to apply for ethics approval if you have not done so already. You should have an ethics section in your proposal that describes the steps you will take to ensure the protection, dignity, rights and safety of potential research participants before, during and after the research takes place. In addition, your IR proposal should describe how you will ensure that universal ethical values and international scientific standards will be adhered to in terms of local community values and customs in planning, conducting and evaluating the research. If you are collecting data in more than one site you may have to apply to more than one ethics board. Agencies will not distribute funds until ethics clearance has been received in writing.

In the ethics section of your proposal, state explicitly how the research will address the following codes of ethics (it may however be worth going to the website of the review board to whom you are submitting your proposal, to make sure you have complied with all their specific requirements):

- Balance potential harm to participants against potential benefits. Possible harms fall into several categories such as physical injuries, loss of privileges, inconvenience (including wasted time, psychological injuries (e.g. embarrassment), economic loss, or legal risks).
- Maintain privacy, anonymity, and confidentiality:
 - when health care providers are research participants;
 - when reviewing medical records;
 - by maintaining the boundary between researchers and physicians.
- Construct the informed consent letter and form (include in proposal appendices).
- Where necessary, include a translation of the consent form in appropriate local language(s) as this may be required by some ethical review committees
- Obtain voluntary consent of all human subjects/participants. In the case of minors, parental/guardian consent must be obtained.
- Make research results freely available as a public good.
- Demonstrate that results cannot be obtained by other methods or means.
- Avoid all unnecessary physical and mental suffering and injury.
- Risks do not exceed the humanitarian importance of the problem the research will solve.
- Cultural diversity considered to ensure participants understand the purpose of the study.
- Adequate provisions taken to protect participants.
- Involve scientifically qualified, well trained and properly supervised individuals in the research team.
- Protocols will be submitted for approval to appropriate ethical and scientific review committees.
- Research procedures involving human subjects will be submitted for approval to an independent ethics committee *before* research begins.
- Research and related procedures will be conducted in adherence to the protocol that received scientific and ethical approval.
- Any alterations to the protocol will be re-submitted for ethics approval.
- Special attention will be paid if the research involves vulnerable subjects.
- Subjects will be informed their participation is voluntary and they are at liberty to withdraw from the research at any time without explanation and/or prejudice.
- Research will be terminated at any stage if there is any reason to believe harm is being caused to the subjects/participants.

- Participants will be provided with the option to receive the results of the study in which they are participating.
- The consent form has two parts: (a) a statement describing the study and the nature of the subject's involvement in it; and (b) a certificate of consent attesting to the subject's consent. Both parts should be written in sufficiently large letters and in simple language so that the subject can easily read and understand the contents. As far as possible, medical terminology should be avoided in writing up the consent form. (These should be included in the proposal appendices).
- It is not anticipated that any participant could suffer harm in this study.

Example

In conducting this study, we will follow the key principles of ethical conduct of research. In the current proposal, we propose to conduct an intervention that we are not certain will work at scale, nor are we certain of the impact (i.e. there is equipoise). Therefore, we have incorporated a control group into our research design. Another key ethical concern is beneficence and justice. The intervention is not invasive and no risks to patients are expected. This intervention may in fact benefit the most vulnerable populations, such as pregnant women and newborn babies. Within this group, it is mainly designed to ensure the poorest can access health care delivery, in case of danger signs, or in case of a sick baby. Efforts will be made to improve health units to support referral in both intervention and control areas.

A rigorous consent process will be put in place. Approval will be obtained from the district health teams and from the local communities including community groups, traditional birth attendants (TBAs), and community leaders following a detailed sensitization about the goal and objectives of the study, the implementation strategy and the evaluation processes. For the evaluation component, informed consent will be requested from study subjects and the local community, and confidentiality will be assured. No patient-specific data will be collected apart from aggregated figures (e.g. such as the number of women delivering at health facilities). This data will be collected from registers, which are routinely maintained by health facilities. In addition, such data will be restricted to the medical care staff and the investigators directly involved in the study, and the study team records no names. During the study period, anybody in the community found sick by the study team will be referred appropriately.

For the evaluation stage of the intervention, uptake and mortality surveillance consent will not be sought from the subjects. The subjects will be free to accept or refuse, and where necessary, women will be free to consult with their husbands and/or community members before consent. The Safe Deliveries study and the Uganda Newborn Estimated Survival Time (UNEST) already have ethical approval from Makerere University School of Public Health (MUSPH) Institutional Review Board (IRB) and from the Uganda National Council for Science and Technology (UNCST). The current protocol will again be submitted to the same bodies for amendment of ethical approvals. The study will continue using the existing Data Monitoring and Advisory Board, which has been serving both the Safe Deliveries study and UNEST. The DMSB members are local experts, all with PhDs in their respective fields of specialty, and have strong policy linkages. The DSMB will meet annually. The study will be registered as a trial both locally and internationally.

Protocols for social science research involving human participants are subject to review, and necessitate approval, of both a local/national institutional review board (IRB) and where the research is funded by WHO, WHO's Research Ethics Review Committee (ERC), which has

the responsibility for reviewing the ethical aspects of proposals for research involving human subjects that are funded or otherwise supported through WHO. ERC's website can be consulted at http://www.who.int/rpc/research_ethics/en/.

Example consent forms

Templates for consent forms can be found at the WHO research policy page (http://www.who.int/rpc/research_ethics/en/). These templates should be adapted to the local situation in which you elicit informed consent. Please make sure that you use the letterhead of your research institution, not that of WHO's Research Review Ethics Committee.

Ethics checklist

Checklists and other guidance documents for preparing proposals in the manner recommended by WHO's Research Ethics Committee (ERC) are available online at http://www.who.int/rpc/research_ethics/guidelines/en/. Remember to provide all necessary documentation and annexes. The protocol should provide the necessary information and details to comply with the questions proposed in the checklist. Also remember to attach any necessary explanations either in the proposal or relevant accompanying documents.

3. PROJECT PLAN

In this session you will work on your project plan, developing a timeline, describing the research team you need to effectively carry out the research project, and creating and justifying the project budget.

After completing this session, your team will be able to:

- Develop a project plan (work plan/timeline) to guide the implementation and monitoring of your project.
- Develop a work schedule (or GANTT chart) to effectively implement and monitor your project, including the tasks and activities to be performed, roles and responsibilities of team members, as well as main milestones/deadlines to be met.
- Describe the research team (including the knowledge and skills that each team member possesses and how they will contribute to the success of the project).
- Develop a realistic, itemized budget linked to specific objectives and activities.
- Provide information required for the justification of various budget items.

Planning the IR project

A project plan presents a clear indication of the time frame for the project and when each aspect of the project will be implemented. Often a work plan or timeline is displayed most effectively in a graphic, table or spreadsheet. If done well, your timeline will help demonstrate the feasibility of the project in a very visible way. The work plan will identify tasks (i.e. developing surveys, conducting a needs analysis; administering surveys; conducting interviews; developing curriculum; administering an evaluation); when the activity will take place (often over a time period); and by whom (responsibilities and accountability).

Rationale for project plan

There are several important reasons for project planning and its value cannot be overstated. A plan establishes a common goal for the project and a clear understanding of the research process. Effective planning:

- facilitates the development of a project focus;
- ensures consensus around a project development strategy and plan;
- ensures ownership of the project;
- ensures everyone understands who is doing what, when, and how each action impacts the project as a whole;
- enhances teamwork and transparency;
- facilitates project monitoring and identification of issues;
- facilitates project evaluation and reporting;
- provides management/donors with key information for project review.

A project plan identifies each task and activity that will be completed throughout the duration of the project. The plan establishes expectations of team members and standards that must be met. Individual team member's responsibilities are outlined as well as timelines for when each task or activity will be completed. The project plan establishes the magnitude of the project in order to be able to develop an appropriate budget to carry out the plan. It helps anticipate or identify potential barriers or constraints in adhering to the timetable, implementation and/or completion of the project and suggests possible solutions. This is a document that facilitates communication

between and among stakeholders, coordinates procedures, teamwork and collaboration. Your research design and procedures will be instrumental in identifying the tasks and activities that need to be completed in your project plan. In summary, the project plan facilitates systematic monitoring of your project.

Phases of an IR project plan

Project plans are generally presented in three major phases (see Table 12): the planning, implementation and follow-through phases.

Table 12. Main activities associated with project planning phases

Phase	Main activities
Planning	<ul style="list-style-type: none"> • Organize the research group and advisory committee • Determine issues or problems to study and frame the research question(s) around these • Develop a research proposal • Obtain ethical clearance • Identify funding sources and obtain support for IR • Establish budget and financial management procedures • Plan for capacity building and technical support
Implementation	<ul style="list-style-type: none"> • Monitor the project implementation and maintain quality • Pre-test all research procedures • Establish and maintain data management and quality control • Explore with stakeholders interpretations and recommendations arising from the research findings
Follow-through	<ul style="list-style-type: none"> • Develop a dissemination plan • Disseminate results and recommendations • Document any changes in policy and/or guidelines that resulted from the research • Monitor changes in the revised programme • Consider ways of improving the programme that can be tested through further research.

Project timelines

The project's total duration should realistically reflect the time needed to carry out each phase of the project plan. Be sure the plan takes into account the time required for staff recruitment and equipment purchases. The project plan should outline:

- work schedules;
- a description of the tasks to be performed;
- schedule and deadlines within tasks;
- people assigned to the tasks;
- The number of person-days required to complete each task.

The duration of a project has serious consequences in terms of meeting deadlines for deliverables and the final report. Project planning must follow rigorous project management standards. There are commercial software packages available to help prepare and monitor the implementation of a work plan.

Project plans can be presented in a variety of ways (Figures 3–5). Choose the most appropriate style for your particular project's needs, for example: bar chart/Gantt chart.

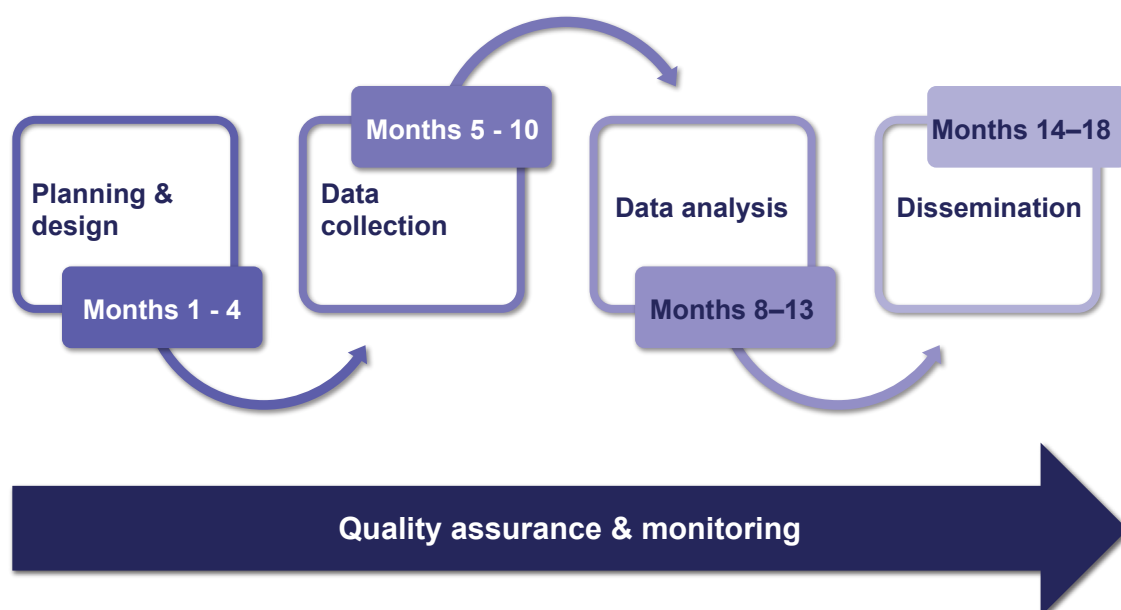


Figure 3. IR project timeline (example)

Year 1			Month							
Activities	Responsible	Supervision/ Support	1	2	3	4	5	6	7	12
1. Preparation										
1.1 Ethical Clearance	1									
1.2 Finalize TSA	1									
1.3 Recruit Researchers and Review Task Assignment	1									
1.4 Instrument Development	1									
1.5 Hiring Field Personnel	1									
1.6 Briefing Research Site Personnel And Authorities	1	/3								
1.7 Local Approval Meetings	1	/3								
1.8 Set Up Bank Account and Field Financial Procedures	1									
1.9 Training Field Personnel and Local Support	2,3	/7,8								
1.10 Pilot Study	2	3/7								
1.11 Final Refinement of Instruments	1	/2								
2. Data Collection, Entry and Analysis										
2.1 National and Regional Policy and Health Services Assessment										
2.1.1 Archival Record Research	3	1/								
2.1.2 Key-Interviews	3	1/								
2.2 Local Health Delivery Assessment										
2.2.1 Archival Record Research	3	1/								
2.2.2 Key Interviews	3	1/								
2.3 Environmental/Water Management Study	4,5	/8								

Figure 4. IR project GANTT chart (example)

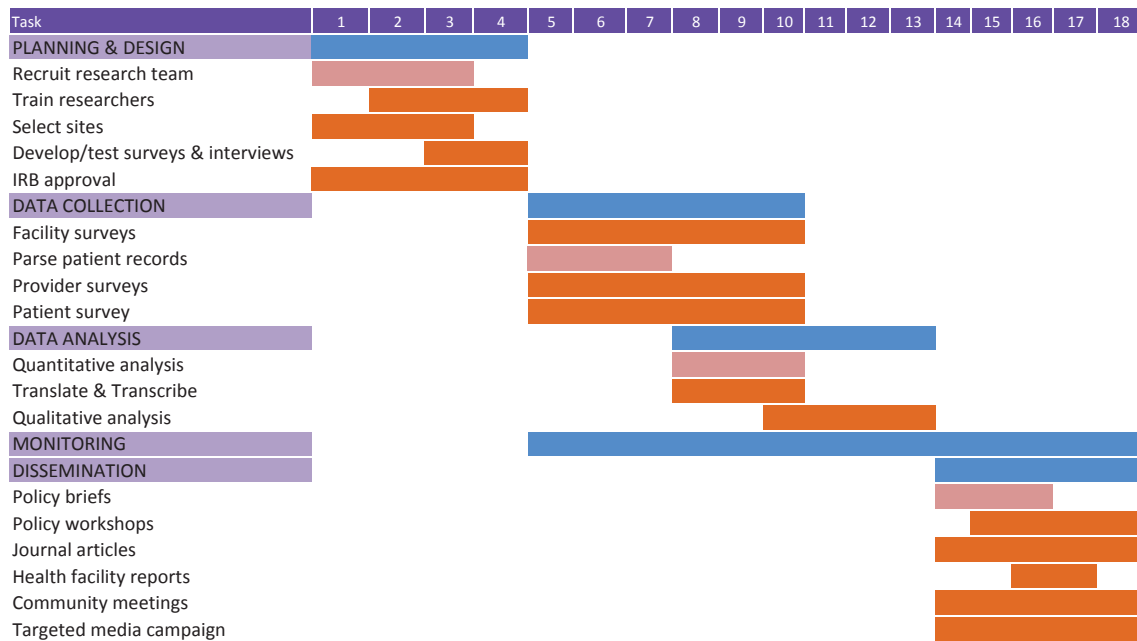


Figure 5. IR project GANTT chart (example)

Research team

The Research team section of your proposal should succinctly describe the members of your team and the assets they contribute to the project. This team will be multidisciplinary and diverse (researchers from academia, health care providers, program implementers, social scientists as well as members of the community). This section should convince the reviewers you have enough expertise on your team to conduct the proposed research effectively. In addition, the proposal needs to include the detailed roles and responsibilities for each of the key team members.

Starting with the principal investigator (PI), list the names of all individuals who will be involved in the study. Include all collaborating investigators, community research partners, research assistants, individuals on training, and support staff. The proposal also includes any “to-be-appointed” positions. Identify the experience and expertise of each team member and how their knowledge and/or skill are essential and add value to the effective completion of the project. Finally, include the role and responsibility of each individual listed on the project.

The members of the research team usually include:

- principle investigator
- project manager(s)
- multidisciplinary key researcher (public health specialist, statistician, social scientist, etc.)
- research assistants
- community members
- collaborators
- advisory committee

Proposals should also include outlines/summaries of the planned research team management structure (see Figure 6 for example) and descriptions of respective roles and responsibilities of team members (see below).

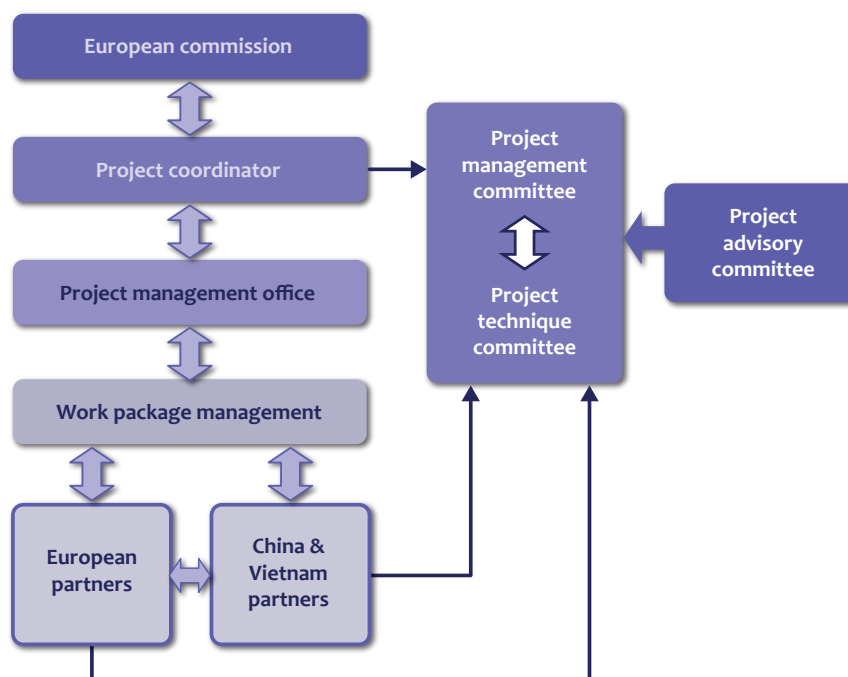


Figure 6. Research team management structure (example)

Example 1. Team roles and responsibilities

Principal investigators: United States (2)

- *Oversee research conceptualization, design and implementation*
- *Liaise between key collaborators, community leaders and research team*
- *Recruit researchers*
- *Supervise community meetings and policy dialogue workshops*

Researchers: United States (2)/Tanzania (2)

- *Analyse data*
- *Train research assistants*
- *Quality assurance*
- *Monitoring and evaluation*
- *Research assistants: Tanzania (10)*
- *Conduct interviews*
- *Collect data for surveys and audits*
- *Enter data into database*
- *In-country coordinators: Tanzania (2)*
- *Administrative assistants: Tanzania (2)*

Example 2. Team roles and responsibilities

ABC University School of Public Health is the applying institution and has the overall responsibility for the project including the day-to-day implementation and management. The school has a financial department that will be responsible for all financial management and reporting requirements in collaboration with the Department of Health Policy Planning and Management. In addition, ABC University School of Public Health, in collaboration with the Ministry of Health, will be responsible for organizing dissemination activities and meetings. The School of Public Health has a strong and long-term linkage with policy and the ministry of health and other key partners, such as WHO, UNICEF, USAID, districts, and the local communities, and is the leading public health academic and research institution in Uganda.

Research team composition

The team comprises a multidisciplinary selection of national and international specialists who will provide the skills that are necessary for the effective design, implementation, evaluation and dissemination of findings that will inform the scale up of maternal, newborn and HIV-related studies, as well as guide the implementation of ongoing programmes. The PI is an epidemiologist who has 10 years' experience working as a district medical officer/MoH and is currently a PI for the UNEST study and lecturer at the School of Public Health. He has also played a key role in several other health system projects. Other members include Dr Jane Doe, a medical officer for reproductive health in the MOH. She will be the main link to policy and, together with the district medical officers, she will provide technical advice that will be crucial for ensuring that the study is aligned with the country's priorities, policies and plans. In collaboration with several local NGOs, Dr Doe also plays a role linking the research team with the relevant policy-makers and providing expert advice on aligning the project with the country's newborn-related priorities.

Other team members from Uganda include Mrs Claire Smith, a health economist and maternal health specialist and Dr David Johnson, a health systems expert with over 30 years of experience. They will be jointly responsible for the costing aspect of the study, as well as the designing of the demand-side financing scheme. Dr John Smith, a consultant obstetrician at CDE University, will be responsible for the training and support supervision of health workers. Dr Jane Davis, a statistician, will be responsible for the design and implementation of the baseline and end line survey. Jane Johnson, a communication specialist, will be responsible for ensuring that study findings are communicated to policy-makers appropriately and in a timely way. The international research team members include John Doe (JHU, health systems expert) the director for the Future Health Systems Program Consortium, Jane Smith (JHU, newborn specialist), David Johnson (JHU, maternal health specialist) and Claire Davis (KI, health systems and policy specialists). They will all play the role of providing technical advice to the team during the design, implementation and evaluation of the study. All research team members will participate in the writing of manuscripts.

The project will recruit two field coordinators, with priority given to those in existing projects, experience already gained and an excellent rapport with the districts and local communities.

Group activity

In teams, use the examples from real IR proposals to reflect on the content presented during the past hour or so, and draft the following sections in relation to your own project:



- The three phases of IR planning.
- The work plan/time line of activities (you can use a simple flow chart or GANTT chart approach).
- The research team, including expertise and roles (a table is one way to display this information effectively).

Budget and Justification

The budget should outline the funds required to be able to effectively conduct the proposed research. You will need to carefully think through what you realistically need from the funding agency(ies) to carry out the project. If your budget is too low or inflated, it can negatively influence the judging of your proposal. One way to assess this is to ask if it is possible to reduce a budget without compromising the quality of the research.

Information such as required funding for each phase of your project is important to outline. Check to see if the funding agency has any restrictions before preparing the budget. Ensure that the budget is presented in the indicated currency, for example. Check with the agency to see if they have suggested/required budget categories that must be used.

If the potential funding agency doesn't have any suggested/required budget categories, organize your budget around a set of meaningful categories that work for your specific project. The types of resources you budget for should align with the proposed activities in the research design. The budget will need to supply the resources necessary to deliver all the proposed research and intervention outputs. Begin by using the project plan to identify the budget you will require for each activity or task. Once each resource is itemized, the unit cost and total cost for the resource can be indicated. Make sure to provide an itemized budget with a detailed breakdown of the funds requested. The budget information should be complete and unambiguous.

If the project plans to extend an intervention to a control population after the study, this also needs to be planned and budgeted for. It is important to also budget for dissemination and evaluation of related activities and outcomes. Find out whether there will be any inadmissible items such as overhead costs. Inflation and currency fluctuation in exchange rates and contingency might affect the budget and final available income. It is important to include mechanisms that will help take care of this.

Budget categories

Categories you may want to consider for itemizing your budget include:

- personnel (salary and benefits)
- researcher (time, salary and benefits)
- training
- consultants and/or resource person (salary)
- instruction
- equipment

- supplies (e.g. paper, toner, batteries, publication cost etc.)
- communication (telephone/postage/Internet/media)
- materials preparation (software, medical supplies, copying and printing)
- travel and subsistence
- community liaison
- rental of facilities
- evaluation
- indirect costs (costs that your organization requires you to include)
- other expenses (lunches for meetings, interviews etc.)

Budget justification

Justify each and every budget item, starting with how the budget items were derived in relation to the activities to be undertaken in your research design. Pay particular attention to major or unusual items (some funding agencies might require extra explanation for anything considered to have major cost). Provide details of additional sources of funding available to the organization or principal investigator. If the funds will go to different institutions, indicate allocation of funds by site.

Example: Budget justification information

Personnel (salary and benefits)

Regardless of the number of months being devoted to the project, indicate only the amount of time (usually in days) being requested for each individual listed for each budget period. Provide names (if known), position and salaries, including percentage for fringe benefits if such benefits represent actual costs to the employer. Fringe benefits should follow institutional guidelines and an understanding of what is/not allowable by the sponsor. Also, make sure to include those who are involved in the project but are not paid (or are not being paid out of the proposal budget). If you plan to involve consultants or other outside personnel, make sure to include all associated costs in the budget.

Provide the names and organizational affiliations of all consultants (include members of external monitoring or advisory committees). Describe the services to be performed under budget justification (number of days, rate of compensation, travel, per diem and other related costs).

Supplies

List the costs of the various categories of expendable supplies (e.g. paper, toner, tapes, film, batteries, printing costs, other field supplies). Itemize supplies in separate categories with amount requested. Justify each purchase.

Equipment

List each equipment item with the amount requested. Include equipment maintenance. Provide justification for each piece of equipment in relation to the work proposed. Identify any piece of equipment considered as major equipment (e.g. major equipment might be any equipment costing more than US\$ 1000) and provide additional information if required.

Patient (research subjects) costs

Explain the nature of the costs (e.g. transportation, drugs for field trials) and method of calculation. It is important to check on limitations linked to the funding organization.

Give details of the locations where patient care will be provided and the budget allocated to each site. Indicate, in detail, the basis for estimating costs, including the number of patients, days of treatment, cost per test or treatment. If both inpatient and outpatient costs are requested, provide information for each separately. If multiple sites are to be used, provide detailed information by site. Include patient travel, patient participation incentives, etc.

Travel

Itemize each travel item. Provide the purpose and destination of each trip and the number of individuals for whom funds are requested. Include the costs of local transportation and field research expenses necessary for carrying out the proposed research. List separately the costs of transportation, subsistence allowance (indicate the scale paid by the institution) and any other costs (specify). Check on limitations linked to the funding organization. Also, some organizations might require separate international and national/local travels cost. Include lodging and subsistence expenses for field workers. Justify the number of trips per year and relate them to individual's tasks. If samples will need to be transported from the field to a lab, indicate how this will happen and the costs involved.

Field costs

Indicate whether there will be a need for renting or purchasing a vehicle and provide detailed justification for why a vehicle is needed. Also make sure to include associated fuel, insurance and maintenance costs. In case a vehicle will be purchased, indicate what will happen to it once the project ends.

Overhead

Find out whether the funding organization will cover overhead costs and include this in the budget accordingly.

Other expenditures

Itemize any other expenditure required for the proposed research to be carried out. This might include things such as insurances cost, outsourcing, publication costs, computer charges, rental and leases, service contracts and communication costs, especially if the work involves many countries/institutions. It is important to note that some organizations do not provide funding for things listed as miscellaneous or other. Make sure to clarify this with the funding organization before submitting the budget.

Group activity

In your IR teams, review the sample IR proposal budget provided by the facilitator(s). Using the information covered in Session 3 and the example budget as a guide, develop a budget for your team's IR proposal.



4. IMPACT

In this session, the sections of your IR proposal that address measures to ensure quality standards in your research project will be reviewed. Specifically, after completing this session you will develop:

- monitoring and evaluation plan for your IR project
- capacity-building plan
- dissemination plan

Considerable effort must be made to ensure that your proposal clearly demonstrates how your research findings will have an impact on the health and/or health care of the communities/populations concerned, policy-making, and on research communities. For example, how will your proposal demonstrate that your research team has:

- Acknowledged, monitored and planned for competing priorities, limited logistic capacity, a lack of political will, and/or inadequate infrastructure and resources – all of which could affect health care packages from being delivered to those who need them most?
- Planned for developing and maintaining capacity building in your IR project to facilitate the adoption of evidence-based health interventions in developing countries?
- Demonstrated that you will disseminate your research findings to ensure your project will generate research evidence to inform policy and programme implementation?

When developing a typical research/academic proposal, the intent is to generate new knowledge and ideas. Conversely, when developing an IR proposal, the intent is to generate research evidence to inform policy and programme implementation. Despite the growing knowledge base on evidence-based practices in health care, there is a large gap between what is known as a result of research and what is consistently implemented in practice. Why is there such a wide gap between what we know and what we do? The fact that it can take years or even decades for research findings, best practices and guidelines to be implemented into health care workers' daily practice is one of the stimuli behind the IR 'movement'.

Utilization of research results is the core purpose of IR. Translating evidence into health care practice requires a monitoring and evaluation process to ensure quality and improve health outcomes. Your proposal should demonstrate that your project will facilitate the adoption and integration of evidence-based health interventions and change practice patterns, particularly in developing countries. In order to be convincing, your proposal should demonstrate that you have considered the complexity of the situation and environments where the research will take place.

Monitoring and Evaluation

A monitoring and evaluation plan:

- Describes exactly how it will be assessed whether or not the project meets its objectives and delivers what has been promised in the proposal.
- Informs the prospective funding agency their investment is/was sound.
- Facilitates the use of research findings for implementation of evidence-based practice and thus improves health outcomes.
- Examines the difference between the implementation effectiveness and efficacy of health intervention.

Monitoring activities

Monitoring activities in your proposal include: steps you will take to assess the progress of the project (e.g. recruitment rate, the extent to which timelines are being adhered to, deadlines concerning required reports to donors etc.) so that any problems or issues can be detected early and any essential changes or interventions can be made as soon as possible.

Monitoring activities include identifying aspects of the project that need to be observed, who is responsible for the various activities and the organization of the monitoring activities. Such monitoring activities are usually associated with specific milestones or timeline events within your project. When identifying your project timeline, consider including your specific monitoring activities. For example, at milestone X you will report on Y.

A description of the monitoring component should include the following:

- Identifying the resources needed for the project, including staff, equipment, supplies, logistics support and funds, and the precautions you will take to ensure these resources will be appropriately used.
- Adherence to the research design procedures to ensure they are being followed correctly and in a timely manner. This includes how you intend to monitor the roles, responsibilities and activities of each team member in relation to the project as a whole in order to ensure the work plan will be carried out as envisaged. Measures that will be taken to identify delays or difficulties.
- Connections between the intervention and quality of data.
- Plans for how the research team intends to communicate and coordinate with the study population, other collaborating groups and/or funding authorities.

Evaluation plan

An evaluation plan should be included in your proposal, outlining exactly how you will demonstrate whether or not your project meets its objectives and was 'successful'. Many research proposal criteria stipulate that approximately 10% of total budget should be designated to evaluation. Often research teams hire a consultant to conduct their evaluation. In your IR proposal, indicate whether the evaluation will be conducted by an internal team member or an external consultant.

The evaluation plan demonstrates how the research objectives will be met and indicates how you intend to keep close track of changes in the project plan and problems encountered and solved (or not solved), so you can inform the stakeholders and include this information in the preliminary report. An evaluation plan should also consider the following:

- Identifies who will use the evaluation findings.
- Describes information needed, sources and evaluation methods/instruments.
- Examines how the project objectives will be met.
- Tracks the expected impact of the intervention.
- Demonstrates that the scope of the evaluation is appropriate.

The evaluation plan will indicate to the prospective funding agency how you will demonstrate that their investment in you will be a good one. If you plan to use a survey or questionnaire to help evaluate the success of your project, include a draft of your evaluation tools in the appendices.

Monitoring and evaluation assesses the success and impact at various stages of the project. Various approaches have been used to measure how well a treatment, programme, or service has been effectively implemented. Some evaluation strategies infer implementation success by measuring clinical outcomes at the client or patient level, while other studies measure the actual

targets of the implementation, quantifying for example the desired provider behaviours associated with delivering the newly implemented treatment. Proctor et al. (6) define implementation outcomes as the effects of deliberate and purposive actions to implement new treatments, practices and services. They propose incorporating the following eight conceptually distinct implementation outcomes into the evaluation plan: acceptability, adoption, appropriateness, feasibility, fidelity, implementation cost, penetration and sustainability.

Include both a concern for formative or process evaluation (evaluation while the project is being conducted) and summative evaluation or product evaluation (evaluation that is conducted during/ at the end of the project to demonstrate the project fulfilled what was originally proposed). If your project is more than one year long, you may want to stipulate that you intend to have annual evaluations and reports. Make direct reference to your research objectives in your evaluation plan, in order to highlight consistency within your proposal.

Your evaluation plan should include a sense of concern for what goes on following the conclusion of the funding period. How will the initiatives that have been started under your project be sustained in the future? How will other cooperating agencies assist in continuing the project after the conclusion of the funding period? To facilitate uptake of your research findings, your proposal should indicate how you intend to inform all stakeholders of your research findings at all stages of the research.

Monitoring and evaluation tools

Monitoring and evaluation strategies that can be implemented to facilitate the quality of your research project include:

- Information log: keeps track of feedback from stakeholders, related news stories reported and articles written, and the number of times research has been cited in the academic literature.
- A survey: conducted with stakeholders from the target audiences to provide feedback. For example, questionnaires can be sent via email six months and one year after a dissemination event, or clients attending a family planning clinic can be asked to complete a survey regarding improvements in the quality of care.
- A series of key informant interviews with stakeholders at various levels of the health system can provide insight into if and how research was used.

One way to display an evaluation plan is to use a table outlining the research objectives or research question(s) and evaluation strategies to evaluate if the objective has been met.

Research objective	How it will be measured
Objective 1	Focus group interview to ... Pre-post surveys
Objective 2	Individual interviews with key stakeholders

Example: Evaluation of intervention process and impact

Objectives

1. *To evaluate the extent to which the revised rural health insurance schemes in the study areas were implemented as planned.*
2. *To explain why or why not implementation occurred as planned.*
3. *To evaluate the impact of the revised health insurance schemes implemented on: improving equity in access to/use of health care; reduction of financial burdens due to expensive medical*

bills; equity and extent of scheme coverage; member satisfaction; and financial viability and sustainability of the schemes.

Description of work

This work package includes a number of work tasks (WT), which aim to undertake a comprehensive evaluation of the intervention impacts, according to the research objectives.

The evaluation will include both a process and an impact evaluation. Parts of the data collection and analysis for the process evaluation will begin simultaneously with the interventions. This is to ensure that effective monitoring of the process of intervention will enable the majority of problems encountered in implementation to be identified and addressed as quickly as possible. Data from a rapid household health survey, qualitative studies, and the management information system operated in the intervention counties and districts, will be used.

WT 1. The first work task is to refine the evaluation frameworks (Figures x and y), which will be used to guide the collection of data for the evaluation. Key researchers and the members of the project advisory committee will use one of the project meetings (to be held at the end of year 2) to discuss how to refine the evaluation framework and finalize it before the completion of the interventions.

WT 2. The research team will also repeat the household health survey using the same methods, the same study counties/districts, and the same population sample as in the situation analysis and baseline survey. The survey will be conducted after completing 18 months of intervention. The questionnaire may be modified to reflect changes made during the intervention period. However, the overall contents of the questionnaire will be the same, covering household general information (e.g. family size, income, insurance membership, etc.), perceived illness (including 1–2 tracer studies – TB suspects/chronic cough patients and diarrhoea patients) and service utilization and expenditure, and reasons for not using services needed, as well as patient satisfaction with services. After completing the survey, all the questionnaires will be entered for analysis based on the evaluation framework developed.

WT 3 Qualitative data will also be collected and analysed, including: focus group discussions using participatory techniques and in-depth individual interviews (with the same social groups in the target population as those consulted in the situation analysis); focus group discussions and in-depth interviews with health service providers at county/ district levels and below, health policy-makers at national and local levels, rural health insurance scheme managers and relevant non-health policy-makers at local levels; semi-structured direct observation will be carried out in selected facilities to assess and compare the behaviour of health staff towards patients who are members/non-members of the revised schemes

WT 4 The relevant data from the management information system operated in the designated health facilities and the insurance fund management organizations will be collected and analysed in line with the evaluation framework.

Deliverables

- *Evaluation framework finalized*
- *Report on impact evaluation of the interventions in the two countries*

Milestones

Finalising the evaluation framework by project month (PM) 20 and writing up the evaluation report by PM 46.

Expected results

More equitable and sustainable health insurance schemes tested in the study areas upon which policy recommendations can be made for the governments of two countries.

Capacity building

Restricted research capacity has been identified as one of the constraints to addressing health care priorities in low- and middle-income countries (7). Generating appropriate, trustworthy evidence depends on the existence of good research organizations. Capacity-strengthening strategies need to focus on the comprehensive needs of institutions, including overall skills and career development, development of leadership, governance and administrative systems, and strengthening networks among the research community, both nationally and internationally.

When writing your IR proposal, two specific considerations may help address capacity building:

- How the project can help improve the research capacity of national and local institutions involved, via training, mentorship, etc.
- How the project, via the process of the implementation, can help increase the capacity of using research evidence for policy- or decision-making by key stakeholders, such as government officials.

Example: Research capacity development

The development and strengthening of research capacity for both partners from China/Viet Nam and Europe will be a continuous process throughout the implementation of the project. The following are key activities aimed for research capacity development.

Each partner should analyse its current situation of research capacity and the gap between what research skills and capacity are required and what are available. A strategy for research capacity building for all the partners involved will then be developed and approved in the first meeting of the project management committee. In light of this strategy, a detailed plan for research capacity building will be developed in the first half of Year 1. The plan will include a system of mentoring and supervision for junior researchers from both developing countries and European countries, and exchange of visiting researchers between Chinese/Vietnamese partners and European partners. The issue of gender will be taken into account in developing such a plan.

A number of appropriate strategies will be used to build up research capacity, particularly for the two developing countries during the project implementation. Researchers from those countries will be invited to visit European partners during the period of the development of study design and research instruments, and data analysis and report/paper writing. While they are with the European partners, these junior researchers will attend a programme aimed at developing their skills in research techniques relevant to the project and analytical issues related to health system development in general and health insurance in particular. Wherever possible, junior researchers will be encouraged to register as Masters/PhD students in their own institutions, with joint supervision by senior researchers from China/Viet Nam and European partners. Junior researchers from European partners will also be encouraged to spend adequate time working in the study field to gain direct experience of undertaking research in developing countries. Junior

researchers from all the partners will also be encouraged to be involved in project management activities in order to enhance capacity of research project management. The strengthening of research capacity of EU partners will ensure a common understanding of key elements of the research, including gender-specific qualitative and quantitative methods and data analysis, health policy analysis, health economics models, etc.

Dissemination plan

An important aspect of your proposal will be the plan for disseminating information of/from the project. Most funding agencies are interested in seeing how their financial support of your project will extend to other audiences. Therefore, your proposal should include a section on Dissemination and will include the kind of dissemination you plan to carry out, and where you intend to disseminate your research findings.

Information dissemination strategy

- To ensure you communicate research information, plans and findings most effectively to stakeholders, answer the following questions:
- What are the objectives of the dissemination strategy?
- Who are the target audiences?
- What are appropriate channels of communication?
- How will you assess information uptake and use?
- What are the most useful tools or products? (e.g. policy briefings, research reports)

Dissemination activities typically include:

- Presentation of research findings at national and international conferences.
- Publication of research findings in national and international peer-reviewed journals.
- Meetings with local and national stakeholders to discuss research findings.
- Policy advocacy briefs.
- Use of life history interviews of patients in advocacy work (with the permission of interview subjects).
- Annual reports.
- Media (e.g. radio broadcasts, press releases, newspaper articles etc.).

This section of the proposal should include:

- An estimate of the number of refereed and professional publications you intend to develop during each year of the project (including the names of journals you will submit to and professional journals, newsletters, printed hand-outs, policy reports and other publications intended);
- The number and names of the academic and professional conferences you intend to attend each year;
- Educational or informal community presentations you propose to make during each year of the project (including workshops or training programs; information sessions; policy briefings; press conferences; slide shows etc).

It is often better to ‘under-promise and over-deliver’ in this regard. Proposals that make elaborate claims (especially without similar track records to support such a publication or dissemination record) tend to lose credibility with reviewers.

Too often, research findings are published in relatively esoteric /highly specialised journals intended for or likely to be understood by only a small number of people with a specialized knowledge or interest and, that are largely only read by other researchers. Disseminating the research findings to all stakeholders in a format suitable for the target audience (key messages) is essential to ensure better use and uptake of research findings.

Group activity

Review the sample dissemination plan (below). What aspects of this dissemination plan may be helpful to consider for your IR proposal? What aspects would not be appropriate?



Example: Consulting with, and disseminating findings to, national policy-makers

The involvement of regional/provincial and national policy-makers throughout the research process is a crucial factor for the success of the project because attaining the expected strategic impact of the research depends critically on them taking up the research recommendations. The following methods will be used to identify key policy-makers, consult with them and communicate the final project conclusions and recommendations to them:

- A stakeholder analysis will be conducted at the beginning of the project and involve the following:
- A project workshop in Project Month 2.
- Key stakeholders identified will be invited to attend joint research planning workshops between both study countries, including the situation analysis and study baseline design workshop in Project Month 4 (see WP 2).
- A workshop to discuss the findings of the situation analysis and discuss possible revisions to existing schemes in Project Month 12 (see WP 3).
- A workshop to present and discuss the preliminary findings of the evaluation of the revised schemes in Project Month 42 (see WP 6).
- A workshop presenting the final study findings in Project Month 47.

Policy briefs will be developed, and aimed at policy-makers and managers at different levels, including regional and national policy-makers. Consultations with primary stakeholders will occur, and they will be provided with full project findings in due course. The primary project stakeholders are the target population, providers of health care and providers of health insurance in the study sites. These groups will be consulted and informed of the findings in the following ways:

- Representatives of primary stakeholder groups such as farmer's associations, and grassroots women's groups will be invited to join the initial project start-up workshop.
- Further consultation will be carried out with these groups prior to the redesign of health insurance schemes through qualitative data collection as part of the situation analysis.
- The preliminary findings of the evaluations of the pilot schemes will be disseminated to representatives of these stakeholder groups through a workshop in month x to enable them to comment on the findings and appropriate recommendations.
- The final study findings will be communicated to these stakeholders through the development and dissemination of appropriate materials such as radio broadcast slots and newsletters.

- Consulting with and disseminating the project findings to international policy-makers and researchers.
- In order to inform the design and implementation of more sustainable, equity-oriented health insurance schemes internationally, it will be important to ensure that the study methodology will produce information on the specific questions and indicators of concern to international policy-makers. The project will involve representatives of international policy makers and their advisers on the technical advisory committee, which will meet twice a year to discuss plans and review results.

The study results will be disseminated more widely through a number of mechanisms, including:

- Submission of academic papers for publication in national, regional and international high impact peer-reviewed journals.
- The production of policy briefings for international policy-makers.
- The presentation of papers at relevant regional and international conferences attended by the health research and policy making community.
- Submission of the final research report to the EU.
- Web-based dissemination of project findings through a project website and submission of the project findings to research dissemination websites such as ID21.
- Presentation to community members, academia, district and regional health teams and other relevant stakeholders.

Write-shop

During the evening, work in your teams to develop the following aspects of your team's IR proposal:

- Monitoring and evaluation plan
- Capacity building plan
- Dissemination plan
- Make any changes necessary to improve, update, or align all sections of your proposal



5. SUPPLEMENTS

In this session you will develop several of the final sections of your proposal. Specifically, information on the project summary, table of contents, appendices, and your researcher CVs will be covered. You will have a write shop to prepare these aspects, and review all the previous components and update and align your entire proposal. Finally, you will prepare a 20-minute presentation and present and receive feedback on your IR proposal.

By the end of the session, participants will be able to:

- Develop a proposal summary
- Develop a table of contents
- Identify which appendices need to be included
- Develop a template for your CVs
- Prepare a 20 minute presentation summarizing your IR proposal

Project summary

An IR project summary (sometimes called an abstract or an executive summary) briefly describes the entire proposal. Researchers often write their summary or abstract last, when they are best able to concisely describe their research proposal. The summary should include a description of the problem under investigation, a rationale for why the research is needed or important (situated in the literature), the participants, the methodology, the research activities to be undertaken and the expected outcomes or implications of conducting the research. Depending on the requirements of the funding agency, your summary/abstract may be limited to anywhere from 150–200 words (abstract) to a page (summary). Like a research report or journal article, your proposal summary or abstract might be the most important paragraph/page of your proposal because it will be the first thing most reviewers come into contact with when reviewing your proposal. The summary will create the ‘first impression’ with reviewers and may influence whether reviewers choose to fund your proposal or not.

Example: IR project summary

Proposal title: Bringing health care to the vulnerable – developing equitable and sustainable rural health insurance in China and Viet Nam

Proposal acronym: RHINCAV

Overall objective: The goal of the project is to contribute towards poverty reduction and health improvement for people living in poor rural areas of developing countries. The overall objective of the project is to promote equity in health by making evidence available for health policy-makers for an effective, sustainable and affordable rural health care financing system in China and Viet Nam.

Specific objectives

- 1. To carry out a situation analysis of perceived needs for rural health insurance and strengths and weaknesses of existing schemes.*
- 2. To develop and implement pilot rural health insurance schemes that are feasible and meet the perceived needs of their target populations.*

3. To monitor and evaluate the effects of the new schemes from the perspectives of equitable coverage, user satisfaction, efficient service utilization and provision, poverty reduction and sustainability.
4. To support the design and implementation of sustainable, equity-oriented rural health insurance schemes by effective dissemination of the research findings.

Abstract

A growing number of developing countries are developing health insurance schemes to protect people, particularly the poor, from financial catastrophe caused by expensive medical care. Among them are China and Viet Nam, which have experienced rapid economic development and dramatic social changes over the past two decades. All these changes have had profound implications for every aspect of people's lives. Health care financing reforms in the two countries have led health facilities to rely increasingly on user charges, which have resulted in greater financial difficulties in accessing health care, especially for the rural poor.

Although the central governments of both countries have promoted the development of rural health insurance for many years, the population coverage has been far from satisfactory, due to many political, socioeconomic and managerial factors. The proposed research will promote equitable health care financing mechanisms in the two countries by developing and disseminating an evidence base for the design and implementation of sustainable and acceptable rural health insurance schemes. The research project will adopt a case study approach in which a number of study counties and districts where rural health insurance schemes already exist will be selected for implementing revised schemes that are feasible and meet the perceived needs of their target population. It will monitor and evaluate the effects of the schemes from the perspectives of equitable coverage, user satisfaction, efficient service use and provision, poverty reduction and sustainability. It is expected that the final project results (good practice and lessons learnt) will be disseminated to a wide audience and used to inform relevant policies on rural health insurance in China, Viet Nam and other developing countries.

Project summary checklist

The summary should be informative to those working in the same or related fields. A good summary makes it very easy for reviewers to comprehend and evaluate your proposed project according to the review criteria. Although the criteria for a research proposal will vary depending on the funding agency, a summary typically will include a brief description of each of the following:

- The problem (what problem are you trying to solve?).
- A convincing rationale for why this problem is important (i.e. how the proposed research will advance knowledge, improve health care practice etc.).
- Where the research will take place and with whom (sites and participants).
- How the data will be collected and analysed.
- The extent to which the proposed research is innovative.
- The expected results or the impact of conducting the research.
- How the findings will be disseminated.
- The implications (change policy, improve health care practice etc. and who will benefit).

Table of contents

The table of contents organizes the proposal by outlining what is in the proposal and where each item can be found. It presents a convenient list of the topics and sections in a logical sequence 'at a glance'.

Word processing software such as Microsoft Word and Open Office, have the ability to automatically generate a table of contents. You can tag your headings with the appropriate heading style (e.g. Heading 1, Heading 2, Heading 3) and use the *Insert > Table of contents* features.

Appendices

Appendices include those aspects of your project that are of secondary interest to the reader. The reader should be able to obtain all the necessary information from the body of the proposal and will go to the appendices if they need or want additional information. Appendices may include things such as the CVs of members of the research team, research instruments, or letters of support. This is also a place to put additional information you would like the reviewers to have access to but the length restrictions prohibit space for them to be included in the body of the proposal.

CVs of investigators

The CVs of investigators have an influence on the reviewer's assessment of your proposal. You may want to ensure at least one member of your team has IR experience, a good track record and a strong publication record. Complementary qualities such as credibility in the community are equally important.

Usually agencies have a limit of 1–3 pages for an investigator's short curriculum vitae. So investigators will need to shorten their CVs to highlight the most relevant aspects of their professional/academic life to the project and to align with the scope of the funding agency. A template can help investigators to shorten their CVs and to keep them uniform.

Write-shop

In your teams develop the following aspects of your team's IR proposal:

- Project summary (one page).
- Title page.
- Appendices (make a list of all the appendices and add the ones that are ready).
- Researchers' CVs (create a template of the CV components so that all researchers have a similar look and format).
- Review all components of your proposal and update and align.



Group activity: Proposal presentation

Prepare a 20-minute presentation (slide or poster presentation) including the following aspects of your IR proposal

- Title
- Rationale
- Statement of the problem
- Research question(s)
- Research design
- Research method



- Data collection
- Data analysis
- Quality management
- Participants
- Ethics
- Project plan
- Research team
- Budget and justification
- Monitoring and evaluation plan
- Capacity building plan
- Dissemination plan

Group presentation

Present your team's proposal to the large group in 20 minutes. This will be followed by 20 minutes of comments, questions, suggestions and comments from the large group and facilitators.



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