

Health Research Fundamentals
Dr. Manickam Ponnaiah
ICMR-National Institute of Epidemiology, Chennai

Lecture - 21
Preparing a concept paper for research projects

Dear friends, welcome to this session on Health Research Fundamentals. All of you by now, have gone through the basics of research in terms of conceptualizing the ideas, study designs, ethical and scientific conduct of research. I am sure now you are ready, to give life to your research ideas in the form of concept paper. I am going to introduce to you, how to prepare a concept paper for research projects.

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Competency to be gained from this
lecture

- Write a concept paper for a research project



At the end of this session, you will be in a position to write a concept paper for research project.

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The seven steps of a successful protocol

- 1 Identify topic, question and objectives
- 2 Outline a one-page concept paper
- 3 Prepare dummy tables
- 4 Write draft protocol
- 5 Prepare instruments and annexes
- 6 Submit to peer review
- 7 Seek ethics committee review

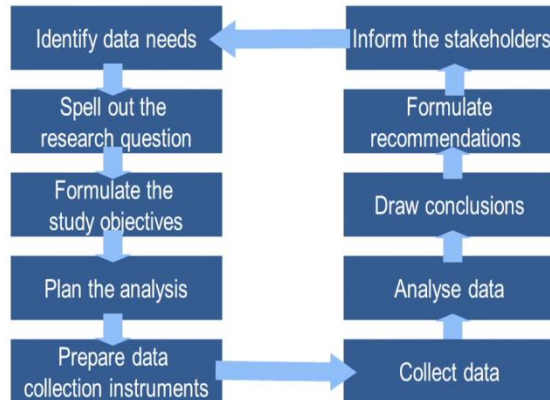


Now, let us revisit the seven steps of a successful protocol. These are logical, sequential and essential steps. The steps include, identifying research topic, framing research question and objectives and then moving on to outlining a one-page concept paper, preparing dummy tables as per the analysis plan, writing a detailed drafted protocol, preparing instruments and annexes including information sheet, consent form and other things related to the study protocol; submit this to your competent peer review committee and finally, seek review by an ethics committee.

Let us look at the life cycle of research and how the steps are important in **relation** to the life cycle of research.

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The life cycle of research



We will see that, we started with identifying data needs and we end with requiring more information that necessitates for the research. So, therefore, in the concept paper has to capture all of these elements in a miniature form of a protocol.

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The seven steps of a successful protocol



We are today in the second step, how do we outline a one-page concept paper? You may wonder, why one-page and there is a reason for it.

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Rationale for using one-page concept paper

- Time is precious
 - For you
 - For your faculty / guide / reviewer
 - For funding agencies
- Brevity forces focus
- Many concept papers are not developed
 - Save time for an idea that may abort



The time, for everybody is very precious for you, for your faculty, for your guides, for your reviewers', time is precious. Equally, the funding agencies are also hot pressed for time. So, a one-page in a shorter version forces you to be focused. Many of our ideas just are not born, they remain as ideas. One page, to write a one page as compared to a long detailed protocol, may help us in overcoming the inhibition that we have in writing the detail protocol. Therefore, the ideas may be born rather than getting aborted, that is the reason for one-page. I am going to now outline this one-page, what it requires in bullet styles in each of the sections of the concept paper.

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Outline of the one-page, bullet-style, concept paper

Background and justification

Objectives

Methods

Expected benefits

Key references

Budget



It has these sections, which is essentially, as I said earlier, miniature of the protocol. It has section on background and justification, statement of objectives as a separate section, method section, expected benefits, key references and budget. I am going to elaborate on each of this section. Let us begin with looking at background and justification.

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Outline of the one-page, bullet-style, concept paper

Background and justification

- Importance of the problem
- What is known and unknown about the problem
- The information that is missing to address the problem effectively



The background and justification essentially will have 3 bullets. One on the importance of the study problem, second what is known and unknown about the problem in relation to the literature and in relation to the local context, lastly the information that is needed to address the problem effectively.

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Outline of the one-page, bullet-style, concept paper

Objectives

- 2-3 objectives
- Can be general and specific
- Can be primary and secondary



Now, let us look at the statement of objectives. In the concept paper, we want you to state not more than 2 or 3 objectives. If needed you may have to split them as general and specific. As we have discussed, in the earlier session on research questions and objectives, you need to indicate which is your primary objective and which are your secondary objectives. This is very critical because the objectives give clarity to the reviewers about your research process.

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Outline of the one-page, bullet-style, concept paper

Methods

- Outline of the methods
 - One bullet per point
- Study design
 - Study population
 - Operational definitions
 - Sampling procedure
 - Sample size
 - Data collection
 - Analysis plan
 - Human participants protection



The next section is on methods. It has to give by bullets an outline of all the aspects of

methods covering, for example, study design, study population, key operational definitions, the sampling methodology by which you will select your study participants, the calculation of sample size and key considerations for sample size. The data collection procedures, who will collect? What will they collect? And an analysis plan around the key objectives. Finally, this section will end up by saying, what are the ethical issues and which ethics committee will review this protocol, if developed.

And next section is on expected benefits. As you have listened from the earlier session, the research question is to be answered. There are two aspects of benefits that we look forward in answering the research question. One, what action will be taken following the results? Second, what is a future research or planning or policy agenda as a result of this finding? This is very important from the concept paper point of view, you have to set out this in this section and finally, you need to show that you have mastered the literature.

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Outline of the one-page, bullet-style, concept paper

Key references

- Not more than 5
- As per standard guidelines
 - e.g., International Committee of Medical Journal Editors-
icmje.org



These key references may be referred to in the introduction section and may be needed to refer to some operational definitions in the method section, citation of a reference. We suggest that you need not put in more than 5 references. However, we recommend strongly, you follow internationally acceptable standard guidelines for writing these references. We recommend, you to adopt and use International Committee of Medical Journal Editors guidelines, which is accepted globally by many bio medical journals.

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Outline of the one-page, bullet-style, concept paper

Budget

- 4-5 lines
- No detailed justification
- Divided in salaries/per diem, travel, equipments & supplies and miscellaneous

The last section is on budget. You may wonder, why budget is important in this concept paper, but it is equally important to technical and other aspects of preparing a concept paper. This is an indicative budget; it need not have detailed justification. It can cover key items like salaries/per diem, travel, equipments and supplies and miscellaneous, whatever is applicable to the **conduct** of the research that you are proposing. Many research agencies insist on having an indicative budget. So, this is also equally important.

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Indian Council of Medical Research (ICMR), Department of Health Research, Govt. of India

The screenshot displays the ICMR website's e-PPMS interface. At the top, the header includes the ICMR logo, the text 'भारतीय आरुविज्ञान अनुसंधान परिषद' (Indian Council of Medical Research), and 'Department of Health Research, Ministry of Health & Family Welfare, Government of India'. Below the header, there is a 'Welcome to e-PPMS' section with a brief description of the system. To the right of this section is a 'Member Login' form with fields for 'Username', 'Password', and 'Forgot Password?'. Below the login form is a 'System Usage Notification' box. On the left side, there is a 'Quick Links' section with several links, including 'The Proposal Submission Process', which is highlighted by a blue arrow. On the right side, there is a 'Broad Areas' section with a list of research areas.

Let us look at some of the aspects of application of this concept. If you look at Indian Council of Medical Research, the premier medical research agency in the country, ICMR on its home page offers funding for researchers, like you and me. There is a provision called extramural funding on its home page and you will see on the home page there is a provision to submit, what they call as pre-proposal format, this is similar to concept paper. This pre-proposal format covers the following, a title, an introduction, a novelty, applicability and description of the project.

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ICMR's pre-proposal format

- Title of the project (*25 words*)
- Introduction (*250 words*)
- Novelty (*100 words*)
- Applicability (*100 words*)
- Description of the project (*700 words*)
 - Methodology, Feasibility, Outcome, Budget, etc



You will see that they have specified word count for each of the section. Now, if you see the outline that be provided, most of this can be taken from the concept paper that we just now, generic concept paper that we just now provided you, except may be, novelty you may have to write it as, in a fresh section.

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ICMR's Short-term studentship (STS) for medical undergraduates: **Format for STS proposals / project**

- Title (25 words)
- Introduction (300 words)
- Objectives (100 words)
- Methodology (800 words)
- Implications (100 words)
- References (300 words)

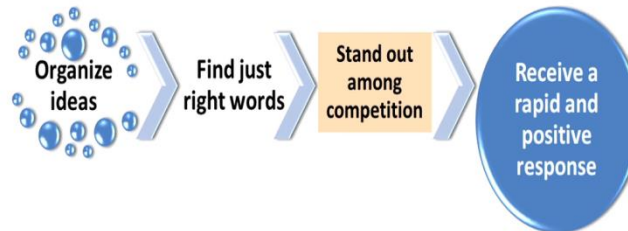


The ICMR is also promoting research culture among medical undergraduates. They are offering, what is called Short-term studentship for medical undergraduates in India, they call it STS proposals. The format for STS proposal, the preliminary one goes like this. It has a title, introduction, objectives, methodology, implications and references. This looks exactly similar to the generic format that we just now recommended. The implication is something similar to the expected benefits that we just now discussed. So, what we are recommending is that, many Indian, other Indian and international agencies accept this pre-proposal or concept note or concept paper as a first step before awarding funding to the researchers. This first step helps them in screening the proposal for its worthiness, merit to award the funds.

In fact, some of the research funding agencies even fund and support developing a concept paper, if it is meritorious to a full pledged protocol through their own funding. So, ready, handy concept paper is very useful to submit to such research funding opportunities.

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What can you achieve with one-page concept paper?

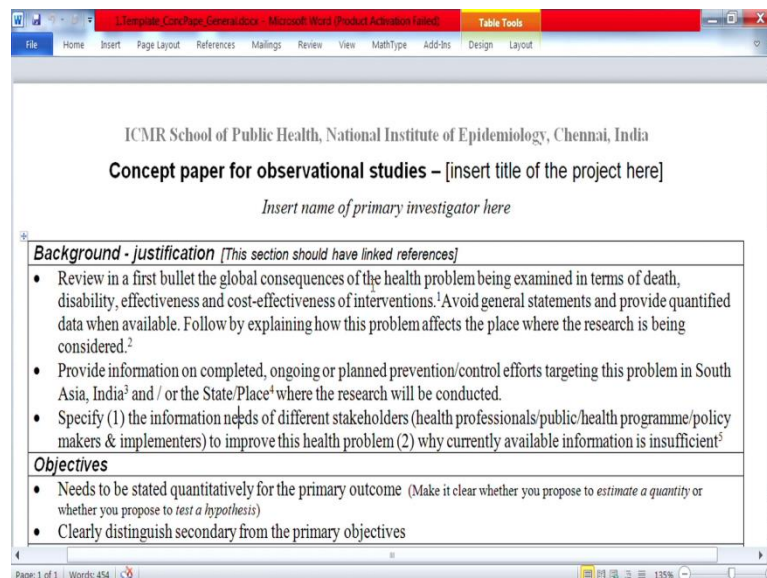


Patrick G Riley. *The one-page proposal*. 2002



Therefore, what can you achieve with one-page concept paper? It helps you to organize your ideas, find just right words in a brief, but succinct manner that helps you to stand out in the competition; you may receive rapid and positive response. For your benefit in the reading section, you will find a template concept paper, one pager, a word document which you may use for writing your concept paper. Second, we have also provided a sample concept paper.

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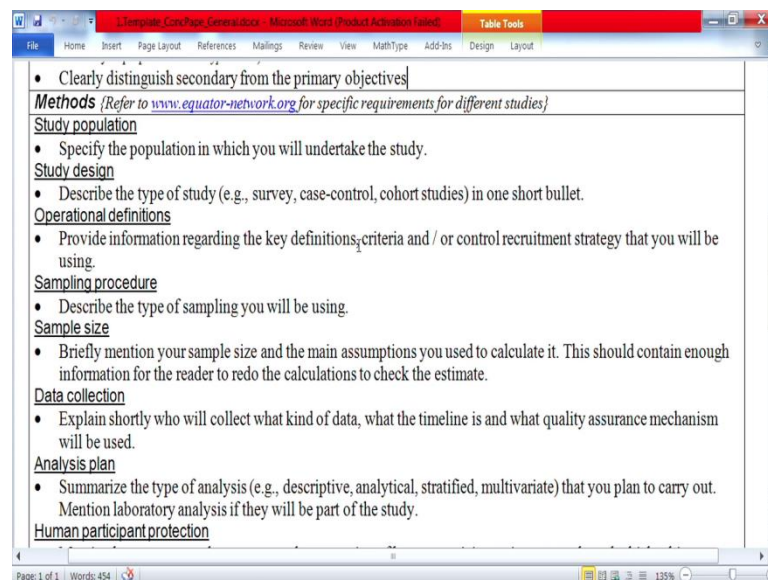


Now, here we look at two templates of concept papers, one for writing observational

studies another for **interventional** studies. I am going to show them and go through the parts of these two templates. The first one is **on** observational studies, as you can see you can type your title of the project, you can type your name, the first section is about background and justification and we have **provided** tips. You can actually, overwrite on these 3 bullets; the first bullet is about the contexts of the study problem in a quantified manner with linked references. The second bullet is about the local contexts, which what we know and what we do not know is stated. The third bullet, in terms of what information we need to manage the problem effectively, you can just overwrite on these 3 bullets.

The next section is about statement of objectives. We have some tips here, you need to state them **quantitatively** for the primary objective and you may make it clear, whether you want to propose to estimate a quantity or test hypothesis depending on the nature of the research question and statement of the objectives, which we discussed earlier. And last, but very important, you need to clearly distinguish the secondary objectives from the primary objectives.

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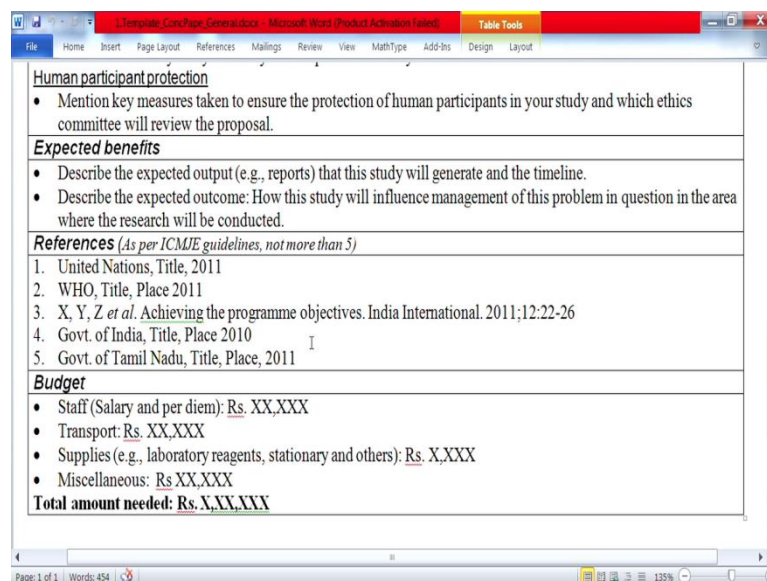
The next section is an elaborate section on methods. As we discussed, it should be in bullets and you can derive from tips for the type of study design from this widely accepted guidelines available in this website, **equator-network.org**. You can state the study population; you can state the study design in one bullet. It could be in terms of

observational study design, it could be a survey, it could be case control cohort studies or ecological studies or sometimes, it could be you know, even case report or case series depending on the study design that you choose, based on the objectives.

Then the **operational** definitions, you need to provide key definitions only and here is where, as I discussed earlier, you can make a reference to the standard definition for the literature criteria. You can even **state** control recruitment strategy for the case control study. Sampling procedure, you can state in one bullet, sample size you can briefly mention the sample size and the assumptions. Data collection you need, as I said, you need to spell out, who will collect the data? What kind of data they will collect and within what time frame? And briefly, the quality assurance that is going to be used, finally, the analysis plan, we need to summarize the type of analysis based on the primary and secondary objectives.

You may mention laboratory analysis, if they are part your study. Human subject production, you may have to mention about key measures that are taken to ensure the **protection** of the human participants and which ethics committee will review this proposal and last, but important section is on expected benefits. You need to describe the report that will be generated and the outcome of the study in order to manage the problem, study problem effectively in the area where the studies conducted.

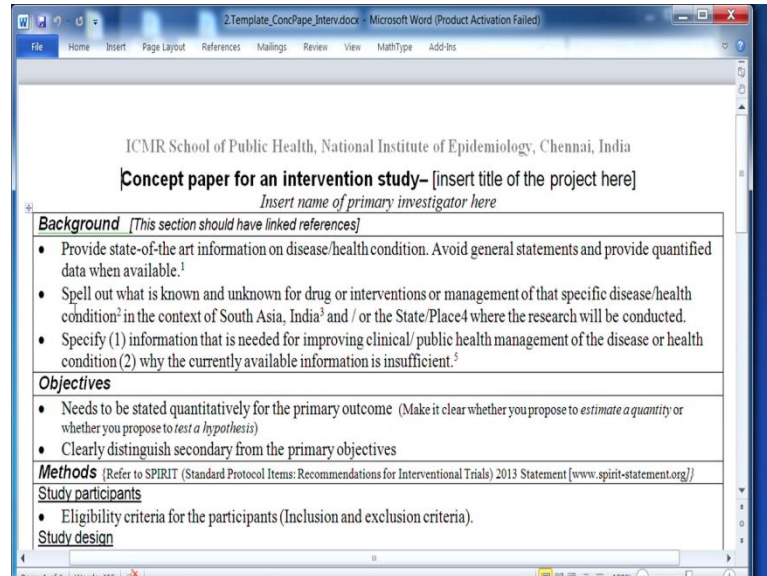
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The references, the 5 references, you can even make it small font size, but adhere to the

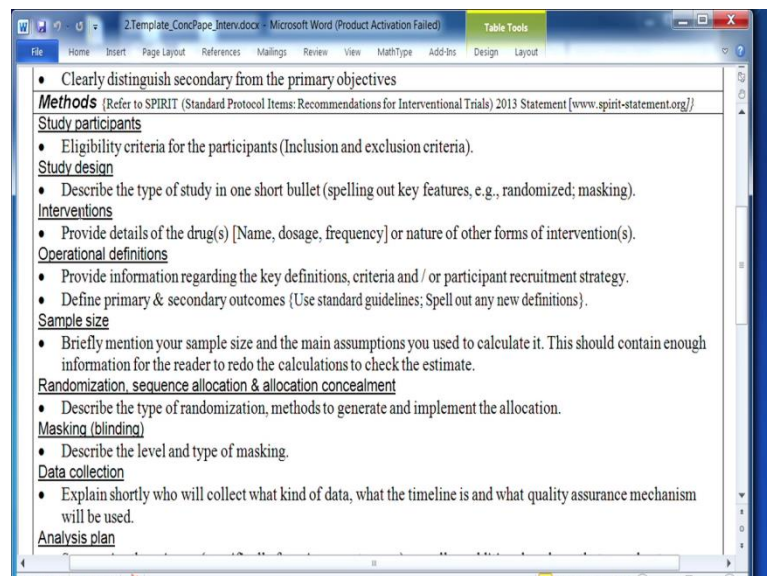
standard guidelines, which we recommend that you use **ICMJE** guidelines. Finally, in the budget section, in a brief or 4 bullets. So, this is on observational studies.

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So, we will now look at concept paper for intervention studies. For intervention studies, the background has to state, what is known and unknown for the drug or interventions or management of the specific study problem that you are talking about and you need to say why the information currently available is insufficient. You need to state the objectives clearly here in terms of primary objective, which will look at the primary outcome.

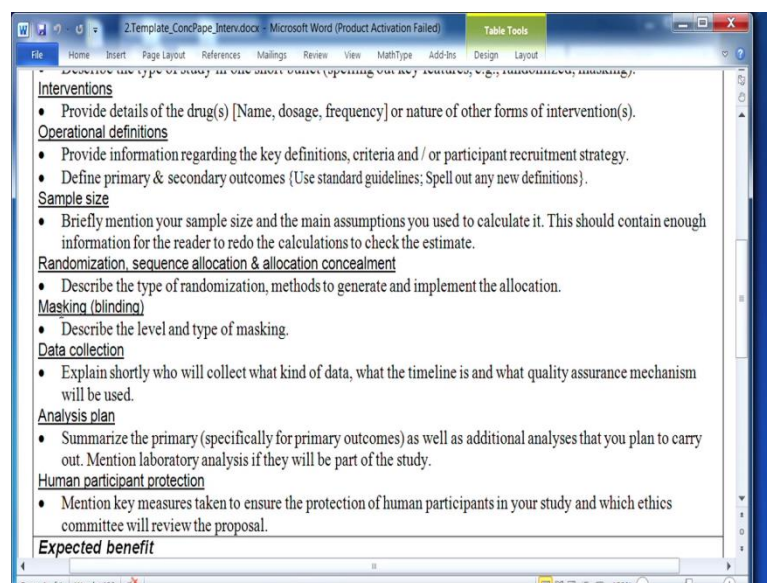
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In terms of methods, you may benefit from using the guidelines that are available for writing a clinical trial protocol. So, you may use the elements from that guideline, which is called SPIRIT. The method section is pretty much similar except that you need to state in the clinical trial concept paper, specifically interventions, the drug or interventions with dosage, frequency, nature and all the other forms of interventions. Operational definitions, you may have to state the primary and secondary outcomes. You may have to state the participant recruitment strategy.

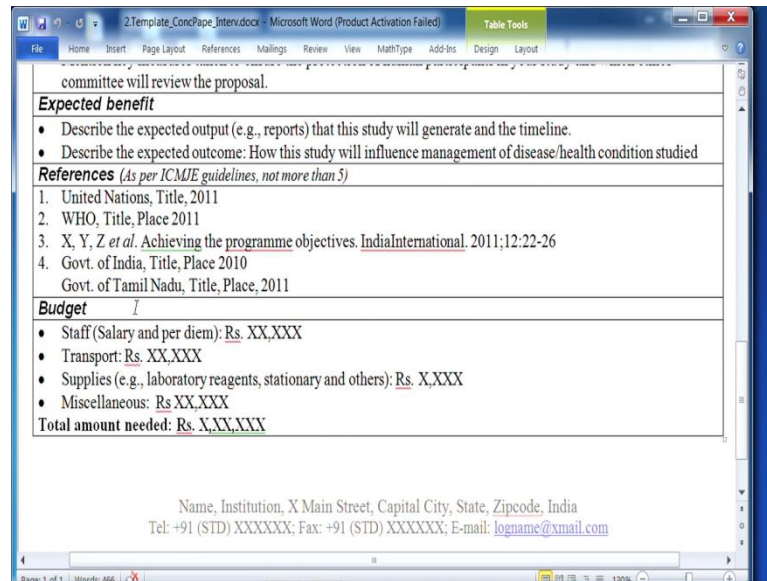
The next important section is on randomization sequence allocation and allocation concealment. You have to briefly mention the type of randomization, methods used to generate and implement the allocation, and masking has to mention as to the level and type of masking.

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The other sections are pretty much similar to what we saw in the concept paper template for observational studies.

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We have a sample out there in the reading section; please make use of it while writing your concept papers. We hope you will benefit by making use of it and make writing concept paper a habit and we wish you give birth to your ideas.

Wish you all the best.

Thank you.