Health Research Fundamentals
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Lecture - 22
Elements of a Protocol for Research Studies

Hello and welcome to this session of Health Research Fundamentals. Today, we are going to talk about the Elements of a Protocol that you would write for a Research Study. Remember, that we are in the last week of the online course and you have gone through all the aspects of how to start designing a research study, starting from thinking about a research question, doing sampling, selecting the research participants, doing measurements for exposures and outcomes, looking after the human subject protection and so forth.

Now, these are all the structures of a research project and when all these structures for a research project come together in a written format and that is what is known as a protocol, which is basically a written plan for a study.

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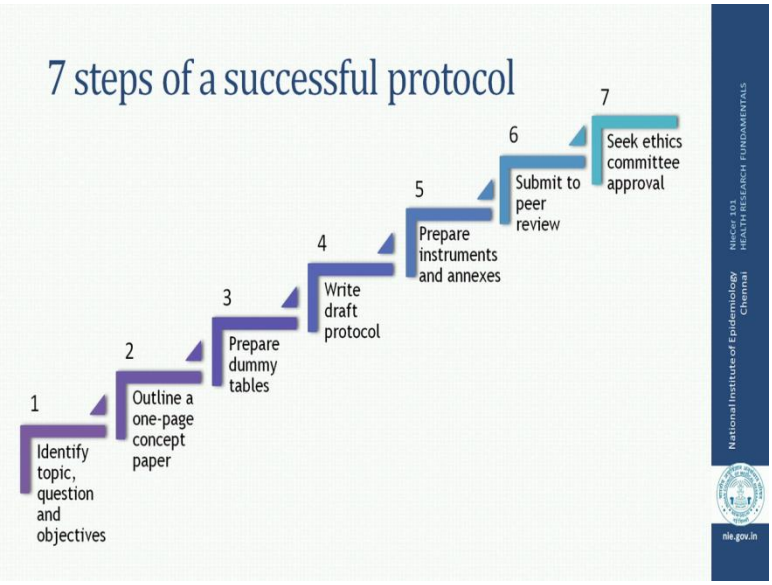

Now, in the last session of writing a concept paper if you remember, Dr. Manickam talked you through the 7 steps of writing a successful protocol, beginning from identifying your research topic and the study objectives, outlining a one-page concept paper, preparing dummy tables and that is when you get on to the part of writing your

protocol. We usually start off with writing a draft protocol and then it is refined adding various elements to it and ultimately ending up with seeking ethics committee approval before you are able to actually do the study.

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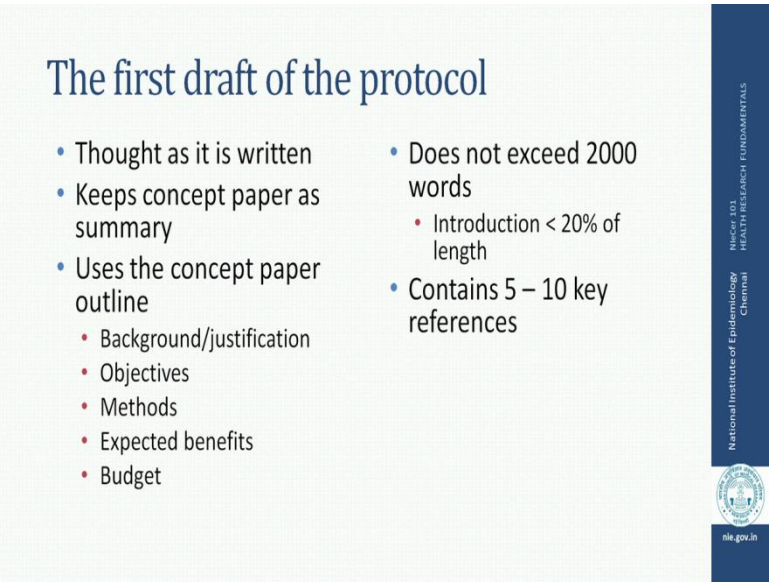

Remember that, when you first start out writing the protocol, you are basically writing it as you are thinking about it and if you already made a concept paper, you are in a good position because you can then just use the concept paper as an outline to actually write in more detail about various aspects that you have already mentioned as bullet points in your concept paper and develop it into a protocol. Usually, the objectives section of your protocol, you would take it as you have stated out already in your concept paper, but the other elements like background and justification, the methods, the expected benefits, these are some of the sections that you would have to now give more elaborate details in your research protocol.

It is also generally a norm that usually the first draft should not to be too long, generally about 1500 to about may be 2000 words with a small introduction, less than one- fifth of the total protocol, which will keep you focused. And of course, remember that, you would given a few references in your concept paper and now you can increase a references, depending on how much detail you are adding to your protocol and so you have may be 5 or 10 or even more key references as is needed for your protocol.

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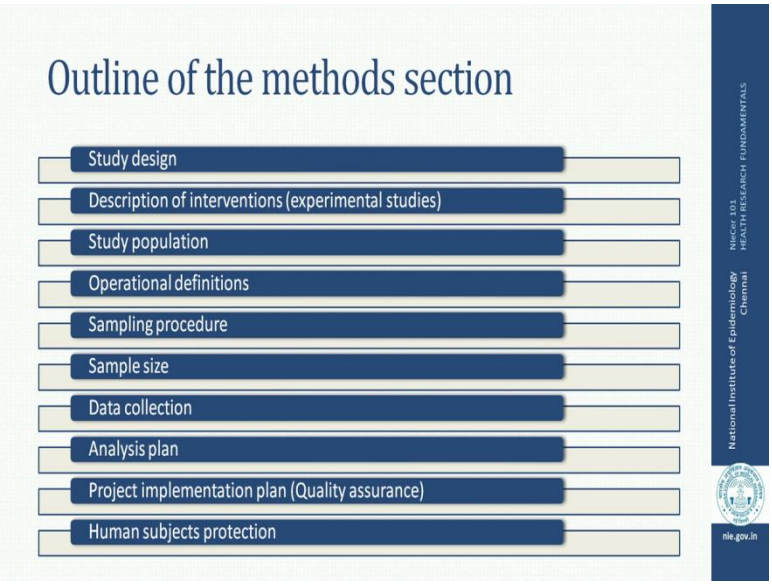

So, as I said, we need much more details and the major part of the protocol would actually be your methods section, wherein you give the whole detailed plan of how you are going to conduct the study, starting from the study design, describing the interventions, if you are doing an experimental study, describing a study population, writing out your operational definitions, what was the sampling method that you used, how did you calculate the sample size, what would be the data collection methods, what would be the tools to do that? What is your analysis plan? And then, a detailed project implementation plan to maintain the quality and finally, the last section on human subject protection. We will walk through each one of these steps, little bit more in detail to see, how you can develop your protocol.

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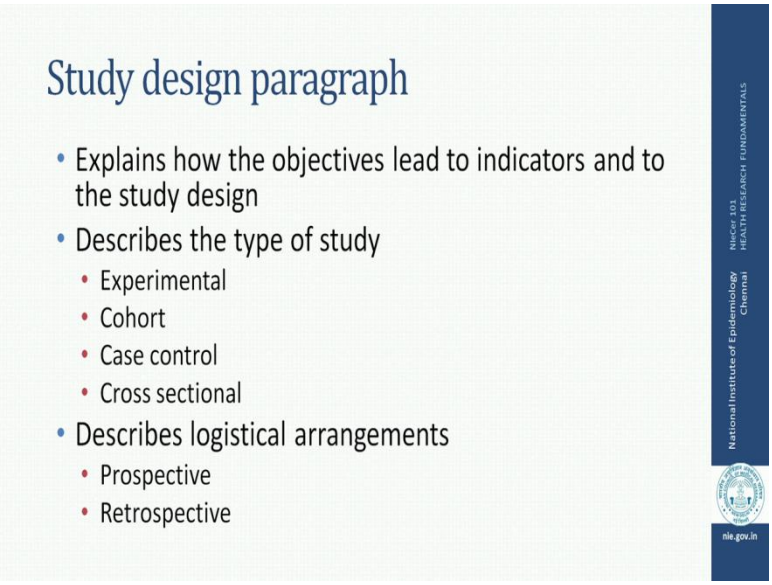

So, in terms of the first paragraph would be the paragraph on study designs. Now, this is where you explain, how the objectives that you have stated at the end of the introduction section, how they would be measured? How would you frame indicators? And what design would be used in your study to fulfill these objectives? Remember, your study design could be experimental or observational; in term it could be a cohort study, a case control or cross sectional study, again, depending on what your study objective is. You need to define again, a little bit more in detail in the protocol, whether your study would follow a prospective design or a retrospective design, in terms of how you are going to collect data and how your study is designed.

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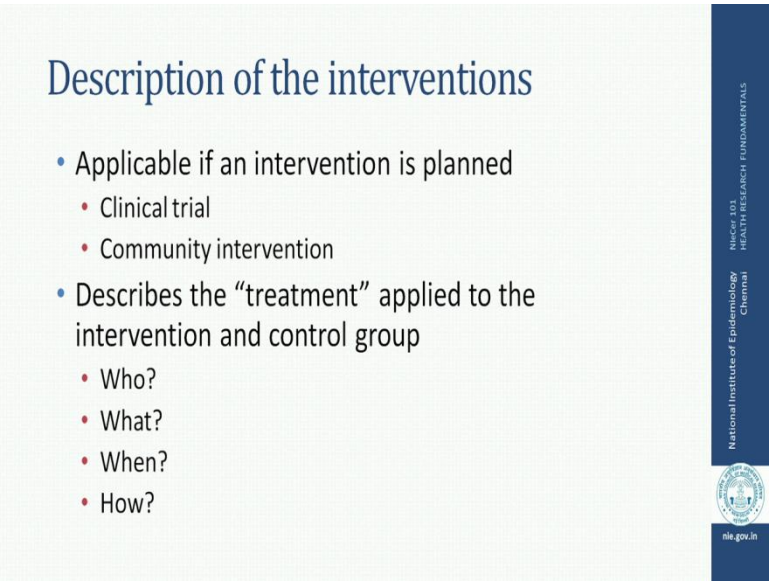

In the next paragraph, you would now want to describe the interventions, assuming that, if you are doing an experimental study, whether it is a clinical trial or a community based intervention. Accordingly, you will describe your intervention, who is going to be intervened, What exactly is your intervention, give it in more detail. What would be the time period over which this intervention is going to be applied to your intervention group and how would, that be done? So, the whole procedure of whether, you are doing a clinical intervention or a community based intervention has to be described in detail in this paragraph, if you are doing an experimental study.

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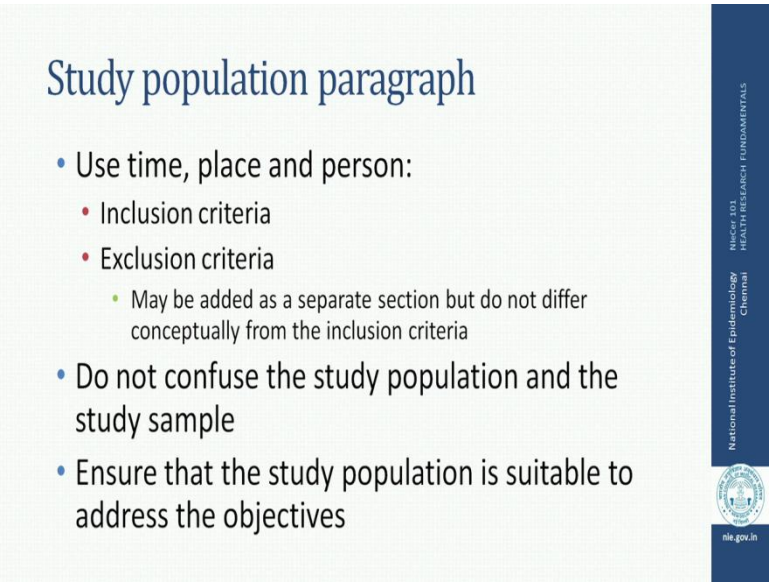

The next paragraph would be detailing about your study population. What is the inclusion and the exclusion criteria that you are going to be using to select the population either, which may be hospital based, community based or population based into your study. You would use over what time period you are going to select this people. What would be, say, the geographical location from where you are going to select this people? And what would be the individual characteristics of the people that you going to select into your study or keep them out of the study, which would be written in the form of an exclusion criteria.

Remember that, study population is different from the actual study sample that you are going to take from this population, or the study population is general population among which you are going to be doing the study and a part of them, you are going to be sampling based on your sample size and sampling strategy into your study.

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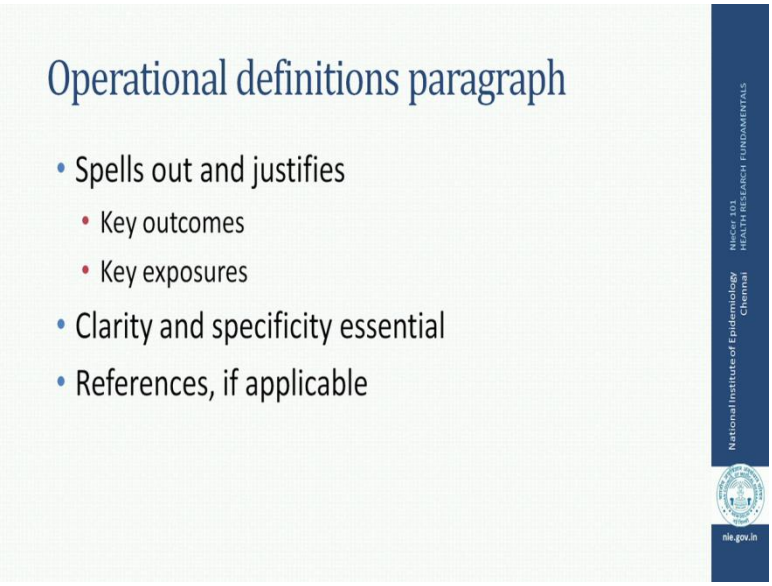

Next paragraph gives the details on the various operational definitions that you are going to be using in your study. You spell out, how you are going to define and measure your key outcome measures. What would be your key exposure measures? And again, what would be the operational definitions of these measures? Remember that, you need to be very clear and specific in terms of these definitions. And many a times, there may be standard definitions, standard ways and means of measuring the outcomes or measuring certain exposures and then it is always good to use these standard definitions and again

for which you would need to provide references, if you are using any of the standard methodologies to define your variables that you are going to be using in the study.

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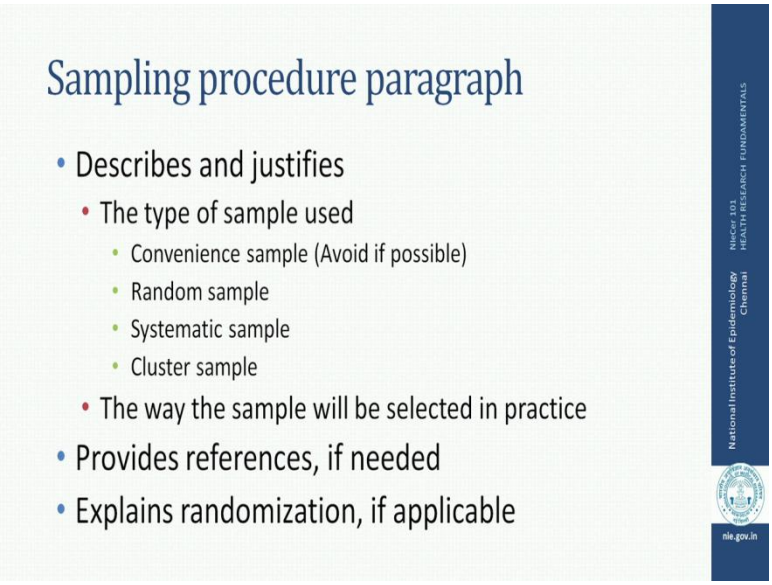

The next paragraph is about sampling. You need to give in detail, what type of sampling you are going to be using, whether it is a random sample or a non random sample, using systematic sampling, simple random sampling, cluster sampling, multi-stage sampling or whatever the case may be, as is applicable to your study and how are you going to select this sample in actual practice. So, all the steps in doing this sampling have to be detailed out in this section of your protocol. Again, if you are using standard methods of sampling, it is also a good idea to provide references of the standard ways in which this has already been applied in other settings.

If you are doing randomized clinical trials then you would be using randomization and as was discussed earlier there are several ways of doing randomization. So, this would be the paragraph, where you would explain which kind of randomization technique you are going to be using and how are the study subjects going to be randomized into your control group and your intervention group.

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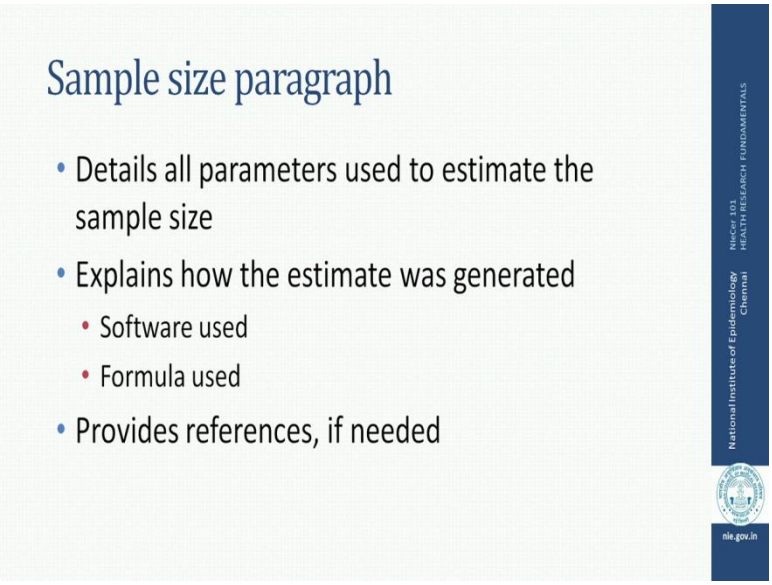

Of course, what follows is the paragraph on sample size, where you will explain how you have calculated the sample size. What are all the parameters that you have used to estimate the sample size? Remember that, the sample size will depend on their study objective as well as the sampling methodology that you are going to employ for your study. You further need to give in detail, how this estimate is generated, what formulas were used, whether you will be using any softwares for doing that? And again, you need to provide references for these things.

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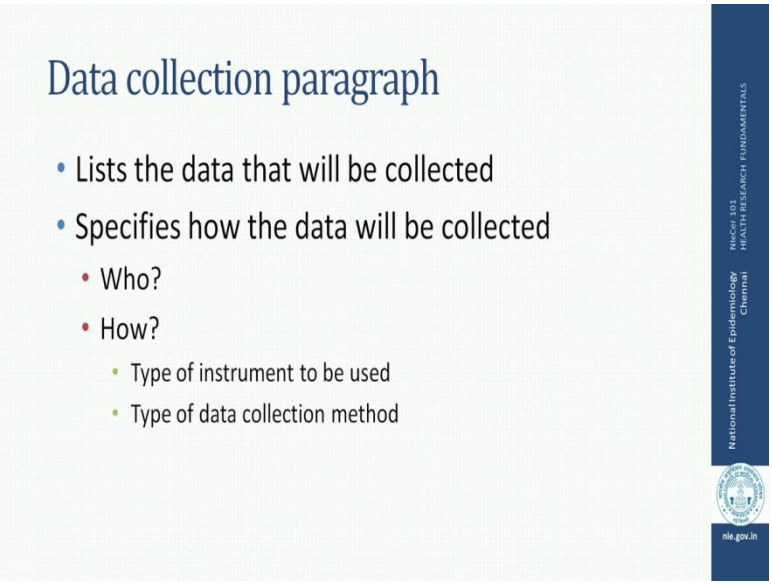

Following the sample size is the paragraph on data collection. There would be 2 sections to this paragraph: one part is where, what is all the kind of data that you are going to collect? Whether it is socio demographic characteristics, the individual characteristics of the study participants, their clinical histories, the science and symptoms and so forth. Secondly, you would also need to specify, how you are going to collect this data. Who is going to do that? What data is going to be collected by the principle investigator or is it going to be some other study investigators, who are going to collect it? Is it going to be a staff nurse? Is it going to be an outreach worker and so forth.

And of course, how you are going to collect this data. What study instrument are you going to be using to collect this in data? Are you going to be doing interviews? Are they going to be face to face? Is it going to be computer based? Are you going to extract data using data abstraction forms? Or if you are doing qualitative methods, would you be doing focus group discussions or in-depth interviews? And what would be the guides for collecting this kind of data?

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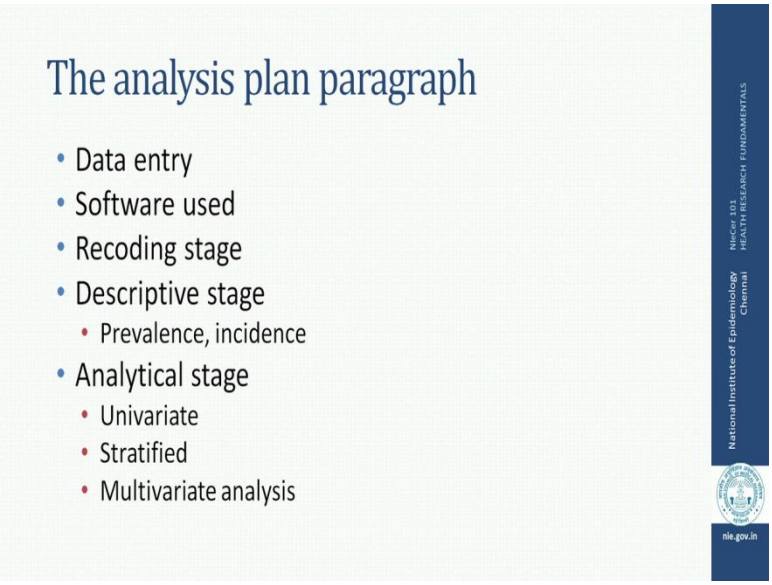

Once, you have spelled out your data collection methods the next paragraph will be explaining, how you are going to analyze this data. Once you have collected the data what would be your mode of data entry? Is it going to be manual? Is it going to be computer based? What software are you going to be using to analyze this data? You also need to give in detail various stages that you may go through in doing the data analysis,

if you are going to be recoding certain variables that you are going to collect during your data collection. What are you going to estimate? What parameters? Whether it is prevalence, incidence or if you are doing analytical studies, what kind of analysis are you going to go through and the various steps that you are going to go through that.

So, all of this has to be mentioned in this analysis plan paragraph. It is not just enough to say that suitable analysis will be carried out for this study. That seems quite vague and it is not a good idea. It does not give a good impression; it shows that maybe you are not planned your study well enough. So, it is always a good idea to actually lay out what all analysis you are going to be carrying out to fulfill your study objectives.

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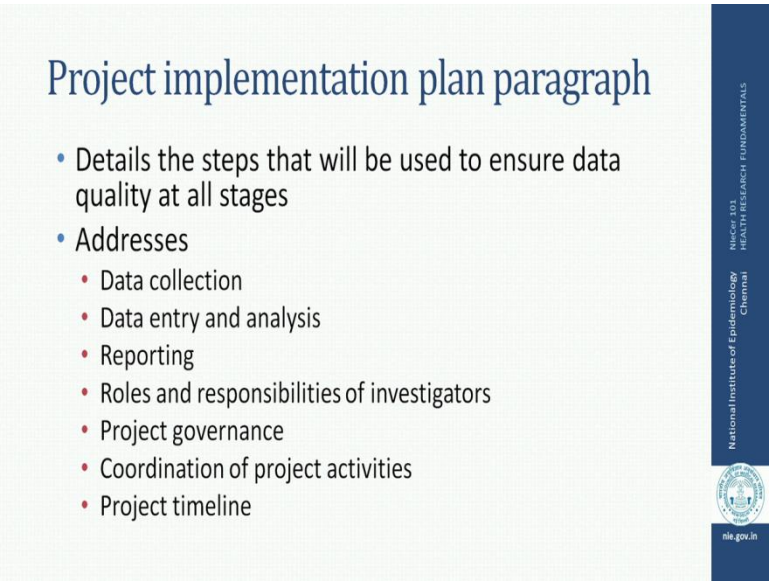

The next paragraph is quite important and it is actually quite a lengthy part of your protocol and which is basically, detailing the steps that you are going to use to actually implement the study to ensure data quality at all stages of the study, in the way you are going to collect the data, in the way you are going to do data entry and analysis, how you going to report these study results. This is also the place, we are going to give in detail the various roles and responsibilities that the investigators in the study have. It is also good place to provide, what would be the project governance? Who would be responsible for this project, both in terms of administrative responsibilities as well as the technical responsibilities? Who is the PI, the primary investigator? Who are the co-investigators? What their roles are and how various project activities are going to be coordinated?

Basically, all the logistics of actually implementing the data collection phase in the field and of course, you need to also provide, what is going to be the timeline for your study? What is going to be your study period? How are different phases of your study starting from say, designing the instruments, getting approvals from ethics committees, then doing pilot testing and then actual collection of data followed by data entry, analysis and so forth? So, you need to give a timeline over the period of your study or for various activities that you are going to be doing as part of implementing your study.

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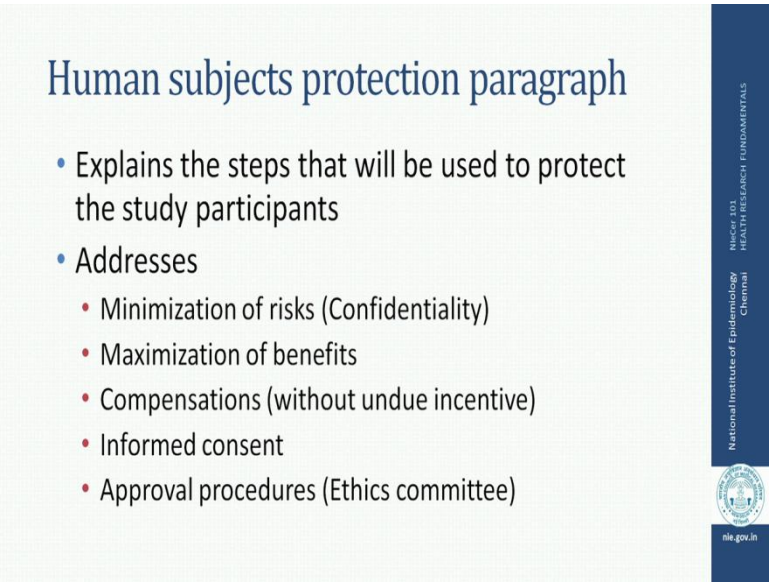

The last paragraph in the methods section is the paragraph on human subjects protection and this is where you explain in detail, how you are going to make sure that your study participants are protected from any harm and here, this would usually have sub-headings in terms of what are the potential risks that you foresee your participants may be going through, when you are collecting data? What are the procedures that you are going to use to minimize these risks? How you going to maximize the benefits? Are you going to give them any compensation?

Again, this is the place, where you give in detail of what kind of informed consent are you going to take from the study participants. Is it going to be a written consent, oral consent? Who is going to take the consent? How long will it take? What would be the various elements of this consent? And then what would be the various procedures that

you would need to get approval for your study from the ethics committee of your institution.

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Now, once you have put together all these elements in the protocol, you also need to append to it, all your data collection instruments depending on your study design, your study objectives and so forth you would have decided what data collection instruments you are going to be using, whether these are questionnaires or abstraction forms, a structured observation guide or if you using qualitative methods and either an in-depth interview guide or a focus group discussion guide, whatever be it. This is the place where you are going to append all of these instruments to your protocol and it is always a good idea to have these instruments in local languages as well because that is how in the field you are going to be collecting data. So, you would have both the data collection instrument in English as well as in the local language.

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And then at the end, what you need to do is to put annexures, which gives in more detail various different components of actual study implementation. These could include things like forms, which state the various standard operating procedures of how you are going to be collecting information, whether this is field based or laboratory based or clinic based and so forth. You may want to provide, how are you going to train your field workers or train your study investigators in collecting data. What would be the training module and the framework for the same? If you have participant recruitment material, that is something that gets appended into the annexes.

Other forms, such as adverse event management forms, study management forms, again would form a part of your annexures and most importantly would be your consent forms, the participant information sheet as well as the consent statement form, wherein the study participant, who would be signing off for agreeing to participate in the study. Again, remember that wherever participants are involved and wherever you have forms that involve participants, you may need to have forms both in English as well as in the local language.

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And of course, once you have put this altogether, you need to firm it up. Remember that, writing a protocol is usually not a one step process. It goes through several drafts and it is always a good idea to actually get it reviewed through your peers, who could be your colleagues or even subject matter experts and get feedback from them and then revise and revise your protocol to get to a final stage, where it can be submitted for review to the ethics committee.

Now, the ethics committee may themselves have certain suggestions or they may want some things to be changed or revised in your protocol. So, you will have to be doing that and so again, this will lead to another draft of your protocol. By the time you are ready with the final draft, you would actually have a multiple drafts and it is always a good idea to archive all these drafts so that you know how your study is evolved and what are the different ways in which you have planned you study.

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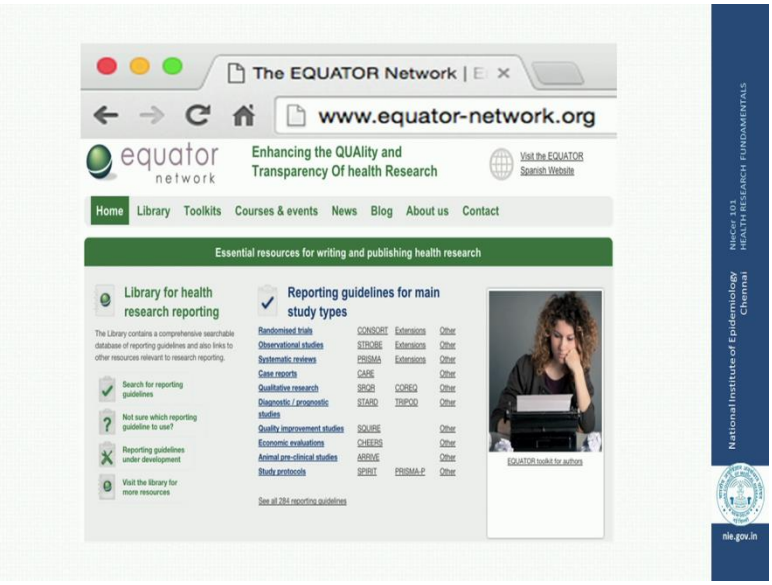

Now, as a resource material, I would like you to take a look at this website, which is called equator hyphen network dot org. And this is a website, which would be very useful for you to develop study protocols. It has a lot of links and a lot of resource material. One of the important one, which is right there on it's home page is what they called the reporting guidelines for main study types and if you look, you have guidelines for observational studies, for experiments, for clinical trials, for qualitative research diagnostic studies and so forth.

And you even have one section on study protocols, so there is the SPIRIT protocol; the SPIRIT guidelines, which basically gives you guidelines on how to write a protocol for clinical trials in particular. And then, the other reporting guidelines, whether it is the CONSORT statement or the STROBE for the observation studies, PRISMA for looking at meta analysis and the systematic reviews, although these are called reporting guidelines, but you could actually use these templates to even make your protocols because ultimately, what you are going to report is going to based on how you have written your protocol.

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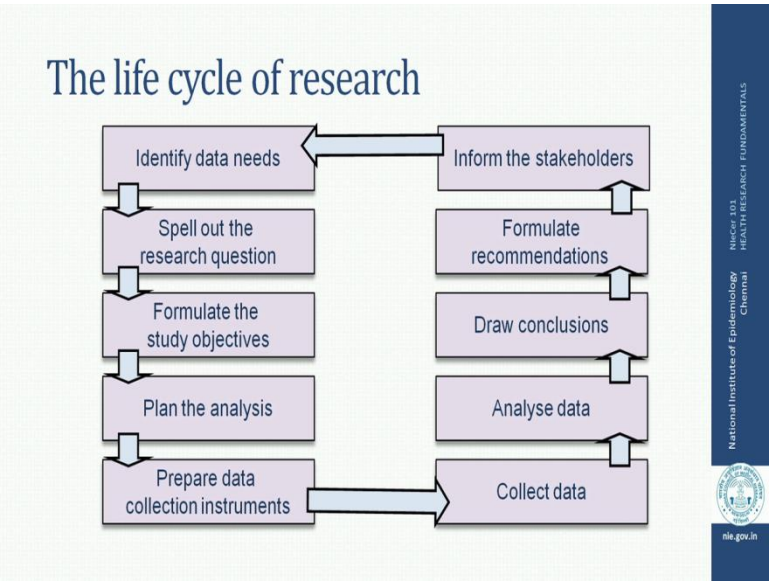

So, remember that, we have come to actually the last week of this course and you would have seen this life cycle in the week one and we have been following this life cycle of research, which takes you through various steps in which you would do a research study and please keep this in mind that following this life cycle is vital to have a study that is logical, that is focused and that is efficient in the way that you are going to conduct the study. So, whenever you are thinking of writing a study protocol, designing a study, make sure you do not jump across the steps of this life cycle and you follow the step one after the other and I ensure you that you are going to end up, with a very good protocol for your study design.

Thank you.