

### **Guidelines for Thesis Protocol**

The thesis protocol is a study plan, designed to describe the background, research question, aim and objectives, and detailed methodology of the study. In other words, the protocol is the ‘operating manual’ to refer to while conducting a particular study.

The minimum writing requirements are that the language should be clear, concise, precise and consistent without excessive adjectives or adverbs and long sentences. There should not be any redundancy in the presentation. The development or preparation of the Thesis Protocol by the candidate will help her/him in understanding the ongoing activities in the proposed area of research. Further it helps in creating practical exposure to research and hence it bridges the connectivity between clinical practice and biomedical research. Such research exposure will be helpful in improving problem solving capacity, getting updated with ongoing research and implementing these findings in clinical practice.

### **PROTOCOL REQUIREMENTS**

1. The Research/Thesis protocol should be restricted to the following word limits:
  - Title: Max Up to 25-50 words
  - Introduction: 1 page (250-300 words)
  - Review of literature: ½ page, 2 recent studies (150-200 words)
  - Aim and Objectives: Each up to 2-3 lines (Up to 100 words)
  - Material and Methods: Up to 2 pages (800 words)
  - References [ICMJE style]: 2-10 references
  - Informed Consent form (Hindi/English): 1 page each
  - Patient information Sheet (Hindi/English): 1-3 pages
2. It is mandatory to have ethics committee and scientific research committee approval before initiation of the research work.
3. The Protocol should be typed in 1.5 space using Times New Roman size 12 font, 1” margins should be left on all four sides. Major sections viz., Introduction, Review of Literature, Aim & Objectives, Material and Methods and References should start from a new page. Study proforma (Case record form), informed consent form, and patient information sheet may be printed in single space.

**Research Ethics:** Ethical conduct during the conduct and publication of research is an essential requirement for all candidates and guides, with the primary responsibility of ensuring such conduct being on the thesis guide. Issues like Plagiarism, not maintaining the confidentiality of data, or any other distortion of the research process will be viewed seriously.

### **Lay out of protocol**

**Title-** A good title should be brief, clear, and focus on the central theme of the topic; it should avoid abbreviations. The Title should effectively summarize the proposed research and should contain the PICO elements.

**Introduction-** It should be focused on the research question and should be directly relevant to the objectives of your study.

**Review of Literature** - The Review should include a description of the most relevant and recent studies published on the subject.

**Aim and Objectives** - The 'Aim' refers to what would be broadly achieved by this study or how this study would address a bigger question / issue. The 'Objectives' of the research stem from the research question formulated and should at least include participants, intervention, evaluation, design.

**Material and Methods-** This section should include the following 10 elements: Study setting (area), Study duration; Study design (descriptive, case-control, cohort, diagnostic accuracy, experimental (randomized/non-randomized)); Study sample (inclusion/exclusion criteria, method of selection), Intervention, if any, Data collection, Outcome measures (primary and secondary), Sample size, Data management and Statistical analysis, and Ethical issues (Ethical clearance, Informed consent, trial registration).

Statistical methods used for analysis should be described specifically for each objective, and name of the statistical program used mentioned.

**References-** Relevant References should be cited in the text of the protocol (in superscripts) using ICMJE style. (For detail refer citing medicine by NLM)

## Some examples of ICMJE style (NLM) referencing

### **Standard journal article**

Halpern SD, Ubel PA, Caplan AL. Solid-organ transplantation in HIV-infected patients. *N Engl J Med*. 2002 Jul 25;347(4):284-7.

List the first six authors, followed by et al. If there are more than six authors, list the first six authors, followed by et al. (Note: NLM now lists all authors.): (Rose ME, Huerbin MB, Melick J, Marion DW, Palmer AM, Schiding JK, et al. Regulation of interstitial excitatory amino acid concentrations after cortical contusion injury. *Brain Res*. 2002;935(1-2):40-6.)

Optional: If a journal carries continuous pagination throughout a volume (as many medical journals do), omit the month and issue number. (Halpern SD, Ubel PA, Caplan AL. Solid-organ transplantation in HIV-infected patients. *N Engl J Med*. 2002;347:284-7)

Optional: Addition of a database's unique identifiers, such as the PubMed PMID, for the citation: (Foroghian F, Yeh S, Faia LJ, Nussenblatt RB. Uveitic foveal atrophy: clinical features and associations. *Arch Ophthalmol*. 2009 Feb;127(2):179-86. PubMed PMID: 19204236; PubMed Central PMCID: PMC2653214.)

Optional: Addition of a clinical trial registration number: (Trachtenberg F, Maserejian NN, Soncini JA, Hayes C, Tavares M. Does fluoride in compomers prevent future caries in children? *J Dent Res*. 2009 Mar;88(3):276-9. PubMed PMID: 19329464. ClinicalTrials.gov registration number: NCT00065988.)

**2. Organization as author** Diabetes Prevention Program Research Group. Hypertension, insulin, and proinsulin in participants with impaired glucose tolerance. *Hypertension*. 2002;40(5):679-86.

**3. Both personal authors and organization as author** (List all as they appear in the byline.)

Vallancien G, Emberton M, Harving N, van Moorselaar RJ; Alf-One Study Group. Sexual dysfunction in 1,274 European men suffering from lower urinary tract symptoms. *J Urol*. 2003;169(6):2257-61.

**4. No author given** 21st century heart solution may have a sting in the tail. *BMJ*.

2002;325(7357):184. **5. Volume with supplement** Geraud G, Spierings EL, Keywood C. Tolerability and safety of frovatriptan with short- and long-term use for treatment of migraine and in comparison with sumatriptan. *Headache*. 2002;42 Suppl 2:S93-9.

### **Books and Other Monographs**

**Personal author(s)** Murray PR, Rosenthal KS, Kobayashi GS, Pfaller MA. *Medical microbiology*. 4th ed. St. Louis: Mosby; 2002. 20.

**Editor(s), compiler(s) as author** Gilstrap LC 3rd, Cunningham FG, VanDorsten JP, editors. Operative obstetrics. 2nd ed. New York: McGraw-Hill; 2002.

**Author(s) and editor(s)** Breedlove GK, Schorfheide AM. Adolescent pregnancy. 2nd ed. Wiczorek RR, editor. White Plains (NY): March of Dimes Education Services; 2001.

**Organization(s) as author** American Occupational Therapy Association, Ad Hoc Committee on Occupational Therapy Manpower. Occupational therapy manpower: a plan for progress. Rockville (MD): The Association; 1985 Apr. 84 p.

**Chapter in a book** Meltzer PS, Kallioniemi A, Trent JM. Chromosome alterations in human solid tumors. In: Vogelstein B, Kinzler KW, editors. The genetic basis of human cancer. New York: McGraw-Hill; 2002. p. 93-113.

**Conference proceedings** Harnden P, Joffe JK, Jones WG, editors. Germ cell tumours V. Proceedings of the 5th Germ Cell Tumour Conference; 2001 Sep 13-15; Leeds, UK. New York: Springer; 2002.

**Informed Consent Form**

**Maharaja Agrasen Medical College Agroha, Hisar (Haryana)**

**Title**.....  
.....

1) I, hereby authorize .....and those whom may be designated as his/her associates to perform Diagnostic/Therapeutic/Investigative procedures.

2. I confirm that I have understood the nature and purpose of the procedures/information for the study (title given as above) or I have been explained the nature of the study by the investigator/doctor, the risk involved and the possibility of complication of the procedures have been fully explained to me. If during the course of the procedure, unforeseen conditions may be encountered or revealed, which may necessitate other procedures in addition to or different from the contemplated ones. I, therefore, further request and authorize the above-named doctor or his/her designates to perform such additional or other procedures.

3. I understand that my participation in this work is voluntary.

4.I am free to withdraw at any time without giving any reason and without having any consequence on my medical care and legal rights. I will also have the opportunity to ask questions.

5.I understand that the Institutional Ethics Committee for human research, the regulatory authorities and the sponsor of the clinical trial/project are free to look at my health records even if I withdraw from the trial. However, my identity will not be revealed to a third party or published. The result and observation of this study work will be used for research work and I DO NOT HAVE any objection to that.

I CERTIFY THAT I ENTIRELY ABIDE WITH THE ABOVE PROCLAMATION AND WILLINGLY READY TO PARTICIPATE IN THIS STUDY.

Signature (or thumb impression) of the subject/person legally authorized to consent:

Name ..... Signature.....Date

Address .....

Signature of the Principal Investigator & Date .....

## **CHECKLIST FOR STUDY SUBJECT'S INFORMED CONSENT DOCUMENTS**

### Essential Element:

- Statement that the study involves research and explanation of the purpose of the research
- Expected duration of the Subject's participation
- Description of the procedures to be followed, including all procedures and
- Description of any reasonably foreseeable risks or discomforts to the subject
- Description of any benefits to the subject or others reasonably expected from research. If no benefit is expected, the subject should be made aware of this.
- Disclosure of specific appropriate alternative procedures or therapies available to the subject.
- Statement describing the extent to which confidentiality of records identifying the subject will be maintained and who will have access to subject's medical records
- Trial treatment schedule(s) and the probability for random assignment to each treatment (for randomized trials)
- Compensation and/or treatment(s) available to the subject in the event of trial-related injury
- An explanation about whom to contact for trial related queries, rights of subjects and in the event of any injury.
- The anticipated prorated payment, if any, to the subject for participating in the trial
- Subject's responsibilities on participation in the trial.
- Statement that participation is voluntary, that the subject can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the subject is otherwise entitled
- Any other pertinent information

### **1.2 Additional elements, which may be required**

- Statement of foreseeable circumstances under which the subject's participation may be terminated by the Investigator without the subject's consent.
- Additional costs to the subject that may result from participation in the study.
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by subject.
- Statement that the subject or subject's representative will be notified in a timely manner if significant new findings develop during the course of the research which may affect the subject's willingness to continue participation will be provided.
- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or foetus, if the subject is or may become pregnant), which are currently unforeseeable
- Approximate number of subjects enrolled in the study

## **STRATEGY for PATIENT-INFORMATION SHEET**

Subjects must be given sufficient information to allow them to decide whether or not they want to take part. An Information sheet should contain information under the headings given below where suitable, and if possible in the order specified. It should be written in easy, non-technical terms and be easily understood by a lay person. Use short words, sentences and paragraphs.

### **1. Title of the research proposal**

Is the title self explanatory to a lay person? If not, an additional simplified title may also be included.

### **2. Incitement Paragraph**

You should explain that the patient is being asked to take part in a research/trial study. The following is an example: "You are being invited to take part in a research/trial study. Before you decide it is important for you to understand why the research/study is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your treating physician/family doctor if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

### **3. What is the rationale of the study?**

The background and aim of the study should be given here

### **4. Why have I been chosen?**

You should explain how and why the patient was chosen and how many other patients will be studied.

### **5. Do I have to take part?**

You should explain that taking part in the research/ trial is entirely voluntary. You could use the following paragraph:-

"It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This will not affect the standard of care you receive."

### **6. What will happen to me if I take part?**

You should say how long the patient will be involved in the research/trial, how long the research/trial will last (if this is different), how often they will need to visit the hospital/lab or and how long these

visits will be. You should explain if the patient will need to visit the doctor more often than for the usual treatment and if travel expenses are available. What exactly will happen e.g. blood tests, x-rays, interviews etc?

Whenever possible you should draw a simple flow chart or plan indicating what will happen at each visit. What are the patients' responsibilities? Set down clearly what you expect of them in the form of simple instructions, for example asking them to come at 8.00 am without having eaten anything/on an empty stomach/fasting. You should explain simply and briefly the research/trial methods you intend to use-the following simple definitions may help:-

**Randomized Trial:** Sometimes, because we do not know which way of treating patients is best, we need to make comparisons. People will be put into groups and then compared. The groups are selected by a computer, which has no information about the individual-i.e. by chance. Patients in each group then have a different treatment and these are compared. This way, the chances of something happening as a result of our choosing to put you in a specific group or bias is reduced. You should tell the patients what chance they have of getting the study drug/treatment: e.g. a one in four chance.

**Blind Trial:** In a blind trial you will not know which treatment group you are in. If the trial is a double blind trial, neither you nor your doctor will know in which treatment group you are (although, if your doctor needs to find out he/she can do so). This is done to ensure that the trial is carried out without a bias that may result from knowing which group you are in, which can adversely affect the results.

**Cross, over Trial:** In a cross-over both the groups have the different treatments in turn. There may be a break between treatments, a washout period, so that the effects of the first drug or treatment are cleared from your body before you start the new treatment.

**Placebo:** A placebo is a dummy treatment such as a pill, which looks like the real thing but is not. It contains no active drug, chemical or ingredient.

### **7. What do I have to do?**

Are there any lifestyle restrictions? You should tell the patient if there are any dietary restrictions. Can the patient drive? Drink? Take part in sport? Can the patient continue to take his/her regular medication? Should the patient refrain from giving blood? What happens if the patient becomes pregnant? Explain (if appropriate) that the patient should take the medication regularly.

### **8. What is the drug or process that is being tested?**

You should include a short description of the drug or device and give the stage of development. You should also state the dosage of the drug and method of administration. Patients entered into drug

trials should preferably be given a card (similar to an identify card) with details of the trial they are in. They should be asked to carry it at all times.

### **9. What are the choices for diagnosis or treatment?**

For therapeutic research/trial the patient should be told what other treatment options are available.

### **10. What are the side effects of taking part?**

For any new drug or procedure you should explain to the patients the possible side effects. If they suffer these or any other symptoms they should report them next time you meet. You should also give them a contact name and number to phone if they become in any way concerned or in case of emergency. The known side effects should be listed in terms the patient will clearly understand (e. g. ‘damage to the heart’ rather than ‘cardio toxicity’ ‘abnormalities of liver tests’ rather than ‘raised liver enzymes’). For any relatively new drug it should be explained that there may be unknown side effects.

### **11. What are the possible disadvantages and risks of taking part?**

For studies where there could be harm to an unborn child if the patient were pregnant or became pregnant during the study, the following (or similar) should be said: “It is possible that if the treatment is given to a pregnant woman it will harm the unborn child. Pregnant women must not therefore take part in this study, neither should woman who plan to become pregnant during the study. Women who are at risk of pregnancy may be asked to have a pregnancy test before taking part to exclude the possibility of pregnancy. Women who could become pregnant must use an effective contraceptive during the course of this study. Any woman who finds that she has become pregnant while taking part in the study should immediately inform the investigator. Use the pregnancy statement carefully. In certain circumstances (e.g. terminal illness) it would be inappropriate and insensitive to bring up pregnancy. There should also be an appropriate warning and advice for men if the treatment could damage sperm which might therefore lead to a risk of foetal damage. If future insurance status, e. g. for life insurance or private medical insurance, could be affected by taking part this should be stated (if e.g. high blood pressure is detected). If the patients have private medical insurance you should ask them to check with the company before agreeing to take part in the trial. They will need to do this to ensure that their participation will not affect their medical insurance. You should clearly state what will happen if you detect or find a condition of which the patient was unaware. Is it treatable? What are you going to do with this information? What might be uncovered (e.g. high blood pressure, HIV status)?

### **12. What are the possible benefits of taking part?**

Where there is no intended clinical benefit to the patient from taking part in the trial this should be stated clearly.

It is important not to exaggerate the possible benefits to the patient during the course of the study, e.g. saying they will be given extra attention. This could be seen as coercive. It would be reasonable to say something similar to:

“We hope that both (all) the treatments will help you. However, this cannot be guaranteed. The information we get from this study may help us to treat future patients with (name of condition) better”.

### **13. What if new information becomes available?**

If additional information becomes available during the course of the research/trial you will need to tell the patient about this. You could use the following:

“Sometimes during the course of a research project/trial, new information becomes available about the treatment/drug that is being studied. If this happens, your research/trial doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, your research/trial doctor will make arrangements for your care to continue. If you decide to continue in the study, you may be asked to sign an updated consent form. Also, on receiving new information your research/trial doctor might consider it to be in your best interests to withdraw you from the study. He/she will explain the reasons and arrange for your care to continue.”

### **14. What happens when the research/trial study stops?**

If the treatment will not be available after the research/trial finishes this should be explained to the patient. You should also explain to them what treatment will be available instead. Occasionally the company sponsoring the research/trial may stop it. If this is the case the reasons should be explained to the patient.

### **15. What if something goes wrong?**

You should inform patients how complaints will be handled and what redress may be available. Is there a procedure in place? You will need to distinguish between complaints from patients as to their treatment by members of staff (doctors, nurses etc) and something serious happening during or following their participation in the trial, i.e. a reportable serious adverse event.

### **16. Will my taking part in this study be kept confidential?**

You will need to obtain the patient’s permission to allow restricted access to their medical records and to the information collected about them in the course of the study. You should explain that all information collected about them will be kept strictly confidential. A suggested form of words for drug company sponsored research/trial is:

“If you consent to take part in the research/trial any of your medical records may be inspected by the company sponsoring (and/or the company organizing) the research/trial for purposes of analyzing the results. They may also be looked at by people from the company and from regulatory authorities to

check that the study is being carried out correctly. Your name, however, will not be disclosed outside the hospital/clinic/laboratory” “All information collected about you during the course of the research/trial will be kept strictly confidential. Any information which leaves the hospital/clinic/laboratory will have your name and address removed so that you cannot be recognized from it.”

**17. What will happen to the results of the research/trial study?**

You should be able to tell the patients what will happen to the results of the research/trial. You might add that they will not be identified in any report/publication.

**18. Who is organizing and funding the research/trial?**

The answer should include the organization or company sponsoring or funding the research/trial (e.g. Govt. agency, pharmaceutical company, NGO, academic institution). The patient should be told whether the doctor conducting the research/trial is being paid for including and looking after the patient in the study. This means payment other than that to cover necessary expenses such as laboratory tests arranged locally by the researcher, or the costs of a research nurse.

**19. Who has reviewed the study?**

You may wish to mention that IEC has reviewed and approved the study (you should not however list the members of the Committee).

**20. Contact for further information**

You should give the patient a contact address for further information. This can be your name or that of another doctor/nurse involved in the study. **(Name of the PI, Address, Telephone Numbers and Name of the Member Secretary of Ethics Committee and address with telephone numbers)**

Remember to thank your patient for taking part in the study! The patient information sheet should be dated and given a version number. The Patient information sheet should state that the patient will be given a copy of the information sheet and the signed consent form.