BASIC PROTOCOL FOR INVESTIGATOR-INITIATIED RESEARCH

NOTE: This page contains instructions on the use of this template and should not be included as part of the protocol.

1. This template can be used for most study designs. It contains the essential elements that the Medical Research & Ethics Committee (MREC) looks for when reviewing a protocol.
2. Users must read the <hints/instructions> carefully and insert relevant information only.
3. Where possible, examples of the information required are shown as <Example: These are suggested information that can be used>
4. If a section is not relevant, do not delete the section. Instead type **NOT APPLICABLE**.

Study Protocol

<Protocol Title>

Protocol number, version number and date:
<Example: Protocol number - XYZ123, Version 1.0, 16 September 2015>

Name and Institution of Principal investigator:
<Example: Dr ERT, Hospital MNB, Kuala Lumpur>

Name and Institution of Co-Investigators:
<Example: Dr HJK, Hospital TGH>
<Example: Dr WER, Klinik Kesihatan IOP>

Name and address of Sponsor:
<Example: Hospital MNB, Ministry of Health>

Study site/s:
<Example:
Hospital MNB
Hospital TGH
Klinik Kesihatan IOP>

Contents

List of Abbreviations

<List commonly used abbreviations/acronyms>

<Abbreviation>	<Full Text>
<Abbreviation>	<Full Text>

Research Synopsis

Study title	<State the full title. Where applicable, suggest title should contain the following information – P (study population), I (intervention), C (comparator), O (outcome), S (study design)> <Example: A randomized double blinded placebo controlled study on the efficacy of drug A in reducing hypertension in patients with condition C>
Study Population	<Include a brief description of the population such as health status, gender, age, etc.> <Example: All adult patients undergoing elective surgery in Hospitals MNB and TGH during the period 1 Oct 2015 – 1 April 2016>
Study Design	<State overview of the study design> <Example: A randomized double blind placebo controlled study. Selected subjects will be randomized into treatment and placebo groups in a ratio of 1:1. Treatment and placebo will be taken at 4 mg b.i.d for 3 weeks> <Example: A retrospective cross-sectional study. Medical records for the period Jan-Jun 2015 of selected subjects will be reviewed and study data extracted>
General Objective	<Insert general objective as stated in OBJECTIVE section below> <Example: To determine the efficacy of drug A compared with placebo, in patients with condition C>
Specific Objectives	<Insert specific objectives as stated in OBJECTIVE section below> <Examples: a. To determine the difference in reduction of blood pressure b. To determine the difference in need for hospitalization>
Study endpoints/outcomes	<Insert study endpoints or outcomes> <Example: (a) change in blood pressure 14 days after initiation of treatment; (b) adverse events during study>
Sample Size	<State total number of participants for the study from all sites> <Example: 40 subjects>
Study Duration	<State period in which study will be conducted> <Example: 1 October 2015 - 31 December 2016>

1.Background and Significance

<This section is based on your research question/area of concern

1.1 Start with what we know about the area, existing knowledge based on what has been published, describe the disease/condition under consideration, including incidence or magnitude of problem. State how others have addressed the issue of concern that we want to study and summarize their findings. Provide a summary of previous pre-clinical studies, relevant clinical studies, any epidemiological data, etc

1.2 Then state what we want to find out or why the concerned areas need to be addressed. Justify your approach to the issue and rationale for specifications of the study interventions. For experimental study, state known information on the investigational product (study drug) / medical device or experimental procedure.

1.3 In the last paragraph state what we want to research upon, the main purpose of the study >

2. Objective

<State the main purpose of the study>
<Example: To determine the efficacy of drug A compared with placebo, in patients with condition C>
<Example: A questionnaire survey on the knowledge, attitude and practices of birth control among sex workers>

3.Methodology

<The methodology explains the procedures that will be used to achieve the objectives. A well written methodology section will enable others to repeat the study exactly>

3.1 Study Type and Design

<Include the description of study type such as aetiology study, diagnostic study, prognostic study, or experimental /intervention study>

<State the study design, for example observatioanl studies such as cross sectional which include survey, cohort, case control, or experimental study such as randomized control trial, interventional case series. State is the data collection prospective, retrospective. . Type of study and design should be decided on the basis of proposed objectives, the study endpoints and the availability of the resources>

In this section, the definition for the endpoints/variables used should be specified in detail, along with the ways and schedule to measure them>

<For interventional or experimental study on drug or medical device:

- Describe and provide rationale for type of intervention, route of administration, dosage, treatment period, etc.
- State how compliance of subject is monitored
- For study on medical device, state specification of the device> State any permitted and not permitted, and rescue medications / treatments during study
- Include information and rationale on use of placebo, washout, withholding treatment, randomization, blinding, etc.>

<State the number of study groups and ratio of subjects in control and treatment group>
<State types and quantity of biospecimens collected and the frequency. State how the specimens are stored and processed. State whether specimens are collected for genetic studies. State whether specimens are collected and used for future studies; include justification>
<For surveys and interviews, describe the instrument such as questionnaires to be used and its rationale>

Include a flow chart to show the sequence of major study activities>

3.2 Study Population
<State where subjects will be recruited from>
<Example: All adult patients undergoing elective surgery in Hospitals MNB and TGH during the period 1 Oct 2015 – 1 April 2016>

3.3 Inclusion Criteria
<State the criteria for including individuals in the study>

3.4 Exclusion Criteria
<State the criteria for excluding individuals from the study>

3.5 Withdrawal Criteria
<State any criteria for withdrawal of subjects. Include follow-up procedures and whether withdrawn subjects are replaced>
<Example: Subjects can choose to withdraw at any time. Subjects may be withdrawn if the investigator deems that it is detrimental or risky for the subject to continue. All withdrawn subjects should attend the final study visit. Withdrawn subjects will not be replaced>

3.6 Sample Size

<Insert calculations for the sample size. Clearly show and justify the parameters used. List the published literature that is referred to for the sample size in event the sample size cannot be calculated>
<Example: Based on a power of 80% (β=0.2), alpha of 0.05, an expected outcome difference of 16% and s.d. of 8% between the 2 study interventions, the calculated sample size for each group is 18 patients. Allowing for 10% dropout, a final sample size of 20 per group will be used>

3.7 Study Duration and Timeline

< State projected start and end dates of study. Briefly state the duration of stages of your study>
<Example:

- Stage 1, review of medical records - 4-6 months
- Stage 2, data collection and data analysis - 8-12 months
- Stage 3, presentation and publication - 6-12 months>

<State duration of each subject's participation>
<Example: The participation duration for each subject is 6 months>

3.8 Study Visits and Procedures

<This section should list the study visits, the observations and measures that will occur at each visit (if applicable). These can be detailed in table format.
List collection of biological specimens, purpose, quantity, frequency, etc.; this includes specimens for genetic analysis. State how specimens are stored and plans for leftovers. Include rationale and justification if stored specimens are to be used for future research. Note that it is MOH policy that the future research must be related to the disease condition or investigation product for which the specimens were originally collected>

3.9 Statistical Analysis Plan

<State the statistical tests to be used. Consult a biostatistician before you finalize your protocol. Include plan of accounting for missing, unused and spurious data. State selection of subjects for data analysis – is it all subjects who have completed study intervention or all subjects who have received at least 1 dose of intervention, etc.>
<Example: The data analysis will be done using the SPSS version 22. Descriptive date will be expressed as mean ± standard deviation (SD) unless otherwise stated. One-way ANOVA will be used for analysis of normally distributed variables. Kruskal-Wallis ANOVA will be used for non-normally distributed data. Categorical data will be analyzed using Chi-square or Fisher's exact test. A value of $P < 0.05$ is considered statistically significant. The data collected will be analyzed using an intention-to-treat basis>

3.10 Risk and benefit to study participants

<Identify any potential or real risks involved while participating in the study>
<Example: As stated in the literature above, there are no serious side effects known to be caused by the investigational product. The study procedures are all routine procedures for the disease/condition studied. There is thus minimal risk for subjects>

<Include any benefits to the participant or to the overall research field>
<Example: This study does not present any direct benefit to the participants. However the study does provide a better understanding of the disease/condition studied>

3.11 Risk Benefit Assessment

<Provide a brief risk benefit assessment. Note that strong justification is needed if the risk outweighs the benefits. State how and where study related injuries are to be treated and who pays for the treatment>
<Example: As stated above, there is minimal risk from the investigational product and study procedures. Study findings shall potentially greatly improve treatment outcomes. The expected benefit outweighs the minimal risk to subjects and thus this study should be supported. If any injuries do occur as a direct result of participating in the study, treatment for such injuries shall be provided or paid for by the sponsor>

3.12 Ethics of Study

<State study will be conducted in compliance with ethical principles outlined in the Declaration of Helsinki and Malaysian Good Clinical Practice Guideline>
< If potentially vulnerable subjects will be enrolled in the study (for example, pregnant and lactating women, children, prisoners, cognitively impaired and critically ill subjects), include a justification for their inclusion. State how these vulnerable subjects will be protected>

3.13 Informed Consent/Assent Process

<State where, when and process for obtaining informed consent/assent. State how informed consent/assent will be obtained from vulnerable subjects>
<Example: Patients shall be informed of the study during their usual clinic visits. They will be requested to contact investigators if they are interested. An appointment will be made where the patient information sheet will be provided and explained to them. If they are willing to participate, the consent forms will be signed and dated. If they need to, they are allowed to take the information sheet home to consult with their family members, and another day for getting consent arranged>

3.14 Privacy and Confidentiality

<State how subjects' personal data will be kept confidential. State the persons who will have access to the data. State how long after completion of study, will data be stored and whether data will be destroyed after that period of storage.

State whether subjects can request access to their personal info and study findings>
<Example: Subject's names will be kept on a password-protected database and will be linked only with a study identification number for this research. The identification number instead of patient identifiers will be used on subject data sheets. All data will be entered into a computer that is password protected. On completion of study, data in the computer will be copied to CDs and the data in the computer erased. CDs and any hardcopy data will be stored in a locked office of the investigators and maintained for a minimum of three years after the completion of the study. The CDs and data will be destroyed after that period of storage. Subjects will not be allowed to view their personal study data, as the data will be consolidated into a database. Subjects can write to the investigators to request access to study findings>

3.15 Conflict of Interest

<Clearly document any consultative relationship that the principal or co-investigators has with any entity related to the protocol that might be considered an apparent conflict of interest. Depending upon the type of conflicts, these can be managed according to institutional policy>
<Example: The investigators declare they have no conflict of interest>

3.16 Publication Policy

<Include a publication policy with regards to maintaining confidentiality of subjects' private information>
<Example: No personal information will be disclosed and subjects will not be identified when the findings of the survey are published>

3.17 Termination of Study

<Insert any criteria for termination of study and subsequent follow-up>
<Example: The sponsor may decide to terminate the study at any time. Subjects will be informed if the study is terminated and follow-up visits will be arranged if needed>

References

<List all the references used>