|  |
| --- |
| **OFFICIAL USE ONLY** |
| **Doc Name :** Study Protocol Template |
| **Doc Number :** IRB-FORM-002 |
| **Doc Version :** 02 | **Date :** 05 Sep 2013 |



**STUDY PROTOCOL**

|  |
| --- |
| **PROTOCOL TITLE:** |
| [Insert Title Here] |
|  |
| **PROTOCOL APPROVAL NUMBER:**  |
| **[Insert IRB Approval Number Here. Indicate ‘NA’ if this is the 1st/initial application]** |
|  |
| **PROTOCOL VERSION:**  | Version Number (e.g., 1, 2, 3) |
| **PROTOCOL DATE:**  | DD MMM YYYY |
|  |
| **PRINCIPAL INVESTIGATOR:**  |
| [Name], [Designation], [Pillar/Department], [Institute] |
| **STUDY SITES:** |
| [Building/Institute], [Address] |
| [Building/Institute], [Address] |
| **CO-INVESTIGATORS** |
| [Name], [Designation], [Pillar/Department], [Institute] |
| [Name], [Designation], [Pillar/Department], [Institute] |
| [Name], [Designation], [Pillar/Department], [Institute] |
| [Name], [Designation], [Pillar/Department], [Institute] |
| [Name], [Designation], [Pillar/Department], [Institute] |
|  |
| **COLLABORATORS:** |
| [Name], [Designation], [Pillar/Department], [Institute] |
| [Name], [Designation], [Pillar/Department], [Institute] |
| [Name], [Designation], [Pillar/Department], [Institute] |
| [Name], [Designation], [Pillar/Department], [Institute] |

**TABLE OF CONTENTS**

[1. BACKGROUND AND RATIONALE 3](#_Toc312946745)

[1.1. General Introduction 3](#_Toc312946746)

[1.2. Rationale and justification for the Study 3](#_Toc312946747)

[1.3. Preliminary Studies 3](#_Toc312946748)

[2. HYPOTHESIS AND OBJECTIVES 3](#_Toc312946749)

[2.1. Specific Aims 3](#_Toc312946750)

[3. STUDY POPULATION 3](#_Toc312946751)

[3.1. Number of subjects to be enrolled 3](#_Toc312946752)

[3.2. Characteristics of subjects 3](#_Toc312946753)

[3.3. Inclusion Criteria 3](#_Toc312946754)

[3.4. Exclusion Criteria 4](#_Toc312946755)

[3.5. Withdrawal Criteria 4](#_Toc312946756)

[3.6. Subject Replacement 4](#_Toc312946757)

[4. STUDY DESIGN & METHODOLOGY 4](#_Toc312946758)

[4.1. Summary of Study Design 4](#_Toc312946759)

[4.2. Sample Size Calculation 4](#_Toc312946760)

[4.3. Study Visits and Procedures 4](#_Toc312946761)

[4.4. Benefits and Risks 4](#_Toc312946762)

[4.5. Difficulties and Limitations 4](#_Toc312946763)

[5. SAFETY MEASUREMENTS 4](#_Toc312946764)

[5.1. Definitions 4](#_Toc312946765)

[5.2. Collecting, Recording and Reporting of Serious Adverse Event / Adverse Event 5](#_Toc312946766)

[6. DATA ANALYSIS 5](#_Toc312946767)

[6.1. Data Collection and Storage 5](#_Toc312946768)

[6.2. Data Quality Assurance 5](#_Toc312946769)

[7. ETHICAL CONSIDERATIONS 5](#_Toc312946770)

[7.1. Informed Consent 5](#_Toc312946771)

[7.2. Waiver of Consent 5](#_Toc312946772)

[7.3. Confidentiality of Data 5](#_Toc312946773)

[8. RECRUITMENT 6](#_Toc312946774)

[8.1. Method of Recruitment 6](#_Toc312946775)

[9. TIMELINE 6](#_Toc312946776)

[9.1. Duration of Research 6](#_Toc312946777)

[9.2. Duration of Subject Involvement 6](#_Toc312946778)

[10. FINANCIAL MATTERS 6](#_Toc312946779)

[10.1. Research Related Costs 6](#_Toc312946780)

[10.2. Industry Sponsored Research 6](#_Toc312946781)

[10.3. Participants’ Incentives 6](#_Toc312946782)

**STUDY PROTOCOL**

|  |
| --- |
| **BACKGROUND AND RATIONALE** |
| General Introduction |
| [Insert Text Here. Briefly describe the background to the current proposal] |
| Rationale and justification for the Study |
| [Insert Text Here. State concisely the importance of the research] |
| Preliminary Studies |
| [Insert Text Here. Provide an account of the Principal Investigator’s preliminary/pilot studies (if any) pertinent to the application.] |
|  |
| **HYPOTHESIS AND OBJECTIVES** |
| Specific Aims |
| [Insert Text Here. State concisely and realistically what the research is intended to accomplish and/or what hypothesis is to be tested.] |
|  |
| **STUDY POPULATION** |
| Number of subjects to be enrolled

|  |
| --- |
| *Give a breakdown by institution for multi-centre studies (if applicable)* |
| Institution/Site of Recruitment | Total | Men | Women | Children |
|  |  |  |  |  |

|  |
| --- |
| **FOR INTERNATIONAL STUDIES ONLY** |
| Total number of subjects targeted for enrolment worldwide |   |

 |
|  |
| Characteristics of subjects

|  |  |  |  |
| --- | --- | --- | --- |
| Lower Age Limit | ***Note****: As the age of majority in Singapore is 21 years old, both parental permission* ***and*** *child assent is generally required before a child below 21 years old can participate in research.***Parental/Guardian consent** should be obtained in writing for all research that involves clinical trials in subjects aged below 21 years. **Exceptions can be granted on a case-by-case basis for non-clinical research that involves “minimal risk[[1]](#footnote-1)[2]” in subjects aged below 21 years.***If the PI is recruiting children above 18 years old but under 21 years old from the public, s/he would need to apply for a waiver of parental consent under section 7.2 of this Form or increase lower age limit to 21 years old (depends on protocol).* | Upper Age Limit (if any) |  |
| Are there any subject recruitment restrictions based on race of the subject? |  |
| Are the subjects vulnerable or in a dependent relationship with the researchers? If Yes, please provide details. |
|  |

  |
| Inclusion Criteria |
| [Insert Text Here.]  |
| Exclusion Criteria |
| [Insert Text Here.] |
| Withdrawal Criteria  |
| [Insert Text Here.]. |
| Subject Replacement  |
| [Insert Text Here.]. |
|  |
| **STUDY DESIGN & METHODOLOGY** |
| Summary of Study Design |
| [Insert Text Here. Discuss in detail the design and procedures to be used to accomplish the specific aims of the research]Please explain what the PI intends to do with potential subjects and the duration of their participation in the research study.If the PI is conducting an experiment, please state what the experiment involves, whether subjects have to attend more than 1 session and how long each session of the research will last. If the PI is conducting a questionnaire survey, please state if personal identifiers, i.e., information that could identify a subject, such as name, matriculation number or contact information, will be collected. Please attach the survey instrument or documents used in the experiment for the IRB’s review. If the survey instrument is not yet finalized, please attach a draft and state in this Form that the PI will submit the finalized instrument for the IRB’s approval when it is ready.If the PI is conducting an interview or focus group discussion (FGs), please consider:* In what language(s) will the interview/ FGD be conducted? If they are conducted in a language other than the English Language, will the documents for subjects, e.g., Interview Guide, PIS&CF, survey instrument, etc, be translated?;
* Where will the interview/ FGD be conducted, e.g., at a time and place convenient for subjects?;
* Is it a once-off interview or will more than 1 session be required. If it is the latter, permission for re-contact should be sought;
* would it be advisable/ appropriate for the PI to show potential subjects the list of questions (or an abridged list) the PI intends to ask when s/he gives subjects a copy of the PIS and before s/he obtains their consent so that they can decide whether or not to participate in the interview/ FGD?; and

Whether re-contact, e.g., for further clarification, is anticipated. If so, permission for re-contact in such cases should be sought.  |
| Sample Size Calculation |
| [Insert Text Here. Include details on sample size calculation and the means by which data will be analysed and interpreted.]  |
| Study Visits and Procedures |
| [Insert Text Here. List all subject-related procedures. Please also describe the subject research visits (frequency and procedures involved). For studies with multiple visits, please include visits schedule.]  |
| Benefits and Risks |
| [Insert Text Here. Describe the anticipated benefits and risks to human subjects participating in this research.] Generally, there are no direct benefits to research subjects participating in the PI’s research study. Please state so if this is the case. |
| Difficulties and Limitations |
| [Insert Text Here. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. Include information on how these difficulties/limitations faced may be minimized or overcome.]  |
|  |
| **SAFETY MEASUREMENTS** |
| Definitions |
| Reportable events, in general, include any incident, experience, or outcome that meets ALL of the following criteria:1. **Unexpected**

In terms of nature, severity or frequency of the problem as described in the study documentation (eg: Protocol, Consent documents etc).1. **Related or possibly related to participation in the research**

Possibly related means there is a reasonable possibility that the problem may have been caused by the procedures involved in the research; and 1. **Risk of harm**

Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized. |
| Collecting, Recording and Reporting of Serious Adverse Event / Adverse Event |
| **Reporting Timeline to the SUTD-IRB.**1. Urgent Reporting: All problems involving local deaths, whether related or not, should be reported immediately – within 24 hours after first knowledge by the Principal Investigator.
2. Expedited Reporting: All other problems must be reported as soon as possible but not later than 7 working days after first knowledge by the Principal Investigator.
 |
|  |
| **DATA ANALYSIS** |
| Data Collection and Storage |
| [Insert Text Here. Describe how is data collected and where the data will be stored. Should your research involves making use of archived/existing databases, please include the necessary documentation, eg., permissions to use those databases. If any part of the procedures will be placed on audiotape, film/video, or other electronic media, state the media and explain how the recorded information will be used and how long will the tapes, etc, be retained and how will they be disposed of.]Please let the IRB know where the data will be stored.If the PI is conducting interviews or focus group discussions (FGDs), please let the IRB know:* if the interviews or FGDs will be audio- or video- recorded. Will subjects be excluded from the research if they do not agree with the recording?;
* if the PI has applied for a waiver of documentation of informed consent (see section 7.2 below) and only verbal consent is taken for interviews/FGDs, the PI may wish to ensure that the subjects’ consent is obtained for the interviews to be taped and the informed consent process recorded.

Some experiments conducted may also be video-recorded or photographed. Where video-recording/ photography is used, please:* 1. Clarify if subjects who do not agree to the recording are excluded; and
	2. note that express consent from subjects should be sought for their photos or video-documentation to be published/ released (with or without identifiers) in any publication relating to the research. The PI should inform them that although their names may not be associated with the video footage or photographs, they may still be identifiable. For example, the PI may ask subjects to indicate in the Consent Form whether they *agree/ do not agree\** for their personal identifiers to be revealed together with their photos/ video documentation in any subsequent publications/ presentations resulting from the research.

Please clarify if **quotes** from the subjects interviewed will be published with identifiers. If so, please state this explicitly in the Participant Information Sheet and obtain each subject’s consent for their comments and/or personal identifiers to be published in a publication relating to the research. For example, the PI may ask subjects to indicate whether they *agree/ do not agree*\* (i) for their comments to be quoted in any subsequent publications resulting from the research; and (ii) for the following personal identifiers to be disclosed in the PI’s academic publication, if any. [ ]  Surname [ ]  First name [ ]  Organisation Name [ ]  Position [ ]  Disagree (I wish to remain anonymous and only agree to be known as \_\_\_\_\_\_\_\_\_\_). |
| Data Quality Assurance  |
| [Insert Text Here. Include details on who will have access to the data, how the quality of the data collected is being monitored, and what will happen to the data after research completion.]  |
| Usually, it would be the Principal Investigators and Co-Investigators who will have access to the data.If personal identifiers, e.g., names, contact information, etc, are collected for the research, please state what will happen to the data after the research is completed, e.g., will the personal information collected be deleted after the research is completed and the data collected coded? The information relating to this question should also be included in the Participant Information Sheet. |
| **ETHICAL CONSIDERATIONS** |
| Informed Consent |
| [Insert Text Here. Summarise the consent procedure. Please specify how will the informed consent be obtained and who will obtain consent. Please submit a copy of the Participant Information Sheet and Consent Form.]  |
| Waiver of Consent |
| [Insert Text Here. Please justify how your research meets the following 4 criteria: (1) The research involves no more than minimal risk to the subjects, (2) The waiver or alteration will not adversely affect the rights and welfare of the subjects, (3) Whenever appropriate, the subjects will be provided with additional pertinent information after participation, and (4) The research could not be practicably carried out without the waiver or alteration. Please also note that all studies involving **deception** must apply for waiver of informed consent (PI is still required to submit the Participant Information Sheet and Informed Consent Form). Subjects in these studies **must** be debriefed.] Please complete this section if the PI is:* Seeking a waiver of documentation of informed consent, i.e., the PI is seeking only verbal consent (as opposed to written consent) from research subjects; OR
* proposing to use incomplete disclosure of information or deception in the study. The PI should then explain in this section why such a technique is necessary and the debriefing statement for the research should be submitted for the IRB’s review.

Please include the following information in the de-briefing material provided to subjects if the PI’s study involves deception or incomplete disclosure of information:* 1. The full title of the research proposal;
	2. An explanation of what information was withheld or what the deception consisted of (if any) and clarifying any mistaken impressions the research participant may have gotten from not knowing this initially;
	3. who the subject could contact if s/he has concerns/ queries regarding the research or the de-briefing materials; and
	4. a statement that the subject is free to withdraw his/her data after being debriefed; and
	5. a statement that subjects will still be awarded their RP credit or reimbursement if they withdrew their data from the research after the debriefing.
 |
| Confidentiality of Data |
| [Insert Text Here. State how will the confidentiality of the data collected will be safeguarded.] |
|  |
| **RECRUITMENT** |
| Method of Recruitment |
| [Insert Text Here. Explain the process of recruitment in detail. For example state how the list of potential research subjects will be obtained. Please submit a copy of any advertisements/posters that will be used.] |
| Please explain how potential subjects will be recruited, e.g., from subject pool, from public, etc, and attach any advertisement, recruitment emails, etc, that will be used for the IRB’s review. The inclusion/exclusion criteria and duration of the subjects’ participation should be clearly stated in the recruitment document. |
| **TIMELINE** |
| Duration of Research |
| [Insert Text Here. State the estimated start and end dates of the research.]  |
| Duration of Subject Involvement |
| [Insert Text Here. Indicate the duration of subject involvement in the research. Please also state the recruitment period.]  |
|  |
| **FINANCIAL MATTERS** |
| Research Related Costs |
| [Insert Text Here. Indicate who will be responsible for research related costs. For sponsored research, list the costs that will be borne by the sponsor.]  |
| Industry Sponsored Research |
|

|  |
| --- |
| **FOR INDUSTRY SPONSORED RESEARCH ONLY** |
| Name of sponsor company |  |
| Address of sponsor |  |
| Sponsor contact person |  |
| Have any of the investigators received any financial support, sponsorship from the company supporting this research? | Yes / No \* Delete accordingly |
| Do any of the investigators hold any ownership interest, e.g. stock options in this company? | Yes / No \* Delete accordingly |
| Is the sponsor offering any incentive connected with subject recruitment or completion of research (e.g. finders’ fee, recruitment bonuses etc) that will be paid to the research staff? | Yes / No \* Delete accordingly |
| If yes, please elaborate: |
| Any other remarks |  |

 |
| [Insert Text Here. State the estimated start and end dates of the research.] - |
| Participants’ Incentives |
| [Insert Text Here. Will subjects receive financial payment/incentive for participation? If yes, please elaborate.]  |

1. [1] The definition of minimal risk from NIH is as follows: Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45 CFR 46.102(h) (i)). [↑](#footnote-ref-1)