**Research Committee – Panel on Research Ethics**

**Sub-Panel on Biomedical Science & Engineering Research Ethics (Human Participants)**

Research Protocol Form

**INVESTIGATOR INITIATED PROTOCOL TEMPLATE**

A research protocol is a document that sets out the plan for a research project in an easily accessible way. It helps to focus ideas and provides direction to guide a project through all phases of its implementation in a consistent manner. Cover page(s) bearing information such as study title, name and department of principal investigator, address information, names of co-investigators may be added to this template at the user’s discretion. Note: If used, the cover page must be revised when there are changes to personnel listed on it.

**INFORMATION REGARDING THE REGULATORY CRITERIA FOR APPROVAL**

All research projects must be developed with the following regulatory criteria for approval in mind:

***1.******Minimization of Risk***

Risk to participants must be minimized:

* by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk.
* by using procedures already being performed on the participants for diagnostic or treatment purposes.

***2.******Reasonableness of Risk***

Risk to participants must be reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result.

***3.******Selection of Participants***

Selection of participants must be equitable taking into account:

* the purposes of the research,
* the setting in which the research will be conducted,
* the special problems of research involving vulnerable populations,
* the selection criteria; and
* the recruitment procedures.

***4. Safety Monitoring***

When appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of participants. When appropriate is generally interpreted by the University of Macau Panel on Research Ethics as follows:

* The Panel on Research Ethics may require that a plan be in place for minimal risk studies, but does not generally do so, and for studies presenting a slight increase over minimal risk for which does generally do so.
* The Ethics Panel will generally require independent monitor be in place for moderate to high-risk studies. In determining whether independent monitor is required the Panel will take into consideration the length of the study, the number of participants to be enrolled in the study, overall participant exposure and other mechanisms for monitoring already in place, e.g. adverse event reporting requirements, access to information from safety divisions etc.
* Issues that should be addressed within the area of data safety monitoring include the frequency of the monitoring, who will conduct the monitoring, what data will be monitored, how the data will be interpreted and analyzed and what actions will be taken upon the occurrence of specific events or end points.

***5. Privacy***

There are adequate provisions to protect the privacy of participants. Note: privacy refers to the individual being.

***6. Confidentiality***

There are adequate provisions to maintain the confidentiality of the data. Note: confidentiality refers to the information collected from/about the individual.

***7. Vulnerable Populations***

When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as minors, prisoners, pregnant women, mentally disabled, persons or economically or educationally disadvantaged persons, additional safeguards are included in the study to protect the rights and welfare of these participants.

***8. Consent***

Provisions are in place for seeking the informed consent of the participant or the participant’s legally authorized representative (LAR). Unless waived or altered by the Panel on Research Ethics, the consent process and form must address the following:

* sufficient time the participant or LAR to consider participation
* the minimization of undue influence or coercion
* information to be provided in a language understandable to the participant or LAR
* that there is no exculpatory language through which the participate or LAR is made to waive or appear to waive any legal rights
* the informed consent does not release or appear to release the researcher, the sponsor, the institution or its agents from liability for negligence
* the required elements of consent

In addition to the noted regulatory criteria for approval, investigators must also ensure that research projects comply with the Health and Safety regulation when protected health information is utilized, and Conflict of Interest regulations when applicable (e.g., study is externally funded and/or involves the testing of a product or service that may have commercial value). Various funding entities may impose further requirements.

**PROTOCOL VERSION # AND/OR DATE:**

*(The protocol version must be revised each time a modification is submitted to the Sub-panel to change the protocol. You may refer to the cover page if the information is provided there)*

**1. Title** *[The title should be short and explanatory.]***:**

**2. Background** *[This section should contain a rationale for the research. Why is the project being proposed? Why is the research needed? This rationale should be placed within the context of existing research or within your own experience and/or observation. Knowledge of the literature surrounding this topic should be demonstrated or, if none is available, a statement should be made to that effect. If there is other work that has covered this area, show how this project will build on and add to the existing knowledge.]****:***

**3. Hypotheses, aims and objectives** *[A hypothesis is a tentative explanation for some occurrence that is to be further explored by investigation. The aim is the overall driving force/goal of the research. The objectives are the means by which you intend to achieve the aims. These must be clear and succinct.]****:***

**Hypotheses:**

**Aims / objectives:**

**4. Study Design & Procedures** *[Describe your proposed study design (e.g. chart review, randomization, comparison groups, pre/post test etc.) and, in order of occurrence, the procedures (e.g. blood draw, surveys, interviews etc.) that will be done and by whom. This section also needs to include details about sample size, subject characteristics, inclusion/exclusion criteria, recruitment, data collection and storage, and methods of analysis. This section should be quite detailed and comprehensive.*

* Study design:
* Screening Procedures and who will perform them:
* Study Procedures and who will perform them:
* Sample size and justification:
* Explain on what basis it is reasonable to assume that the sample size will be obtained:
* Subject characteristics and justifications:
	+ Age:
	+ Ethnicity:
	+ Gender:
	+ Vulnerable Populations
	+ Other characteristics - (e.g. vulnerable populations; primary language etc.):
* Inclusion criteria:
* Exclusion criteria:
* Describe length of subject’s participation in the study including number of visits, frequency of visits, and length of visits:
* Methods of Data Collectionand Types of Data to be collected
* Method(s) of data analysis:

**5. Timetable** *[Provide a detailed timetable scheduling all aspects of the research. This will include data collection (e.g. time taken to administer questionnaires, complete interviews, and abstract data from charts), analyze data, write reports etc. You may reference an attached flow diagram, including expected start and completion dates, and/or describe the timetable here]:*

* Expected Start Date:
* General Time Table**:**
* Expected Completion Date:

**6. Budget/resources:** *[You need to think about what you will need for your research and whether those resources are available to you. The Sub-panel will want to know that you have thought carefully about what resources are needed and from where you expect to obtain these, and whether or not a budget workbook needs to be completed. Some types of research are more resource intensive/expensive than others and you will have to consider this when deciding upon your research method.]:*

**7. Dissemination** *[Describe how you intend to disseminate the results of your research, e.g. dissertation, presentation, web site, journal article.]:*

**8. References/Literature Review**: