Sunway Medical Centre Independent Research Ethics Committee (SREC)

SREC APPLICATION GUIDELINES

ABOUT SREC

SREC stands for the Sunway Medical Centre Independent Research Ethics Committee. It is a committee established to provide independent, competent, and timely review of the ethics of proposed research or studies in Sunway Medical Centre. In providing its review, SREC conforms to the Operational Guidelines for Ethics Committees That Review Biomedical Research (2000) set by WHO. SREC members comprise of multidisciplinary and multisectorial members with relevant scientific expertise as well as laypersons representing the interests and the concerns of the community. The SunMed Clinical Research Centre of Sunway Medical Centre acts as the Secretariat to SREC.

SREC RESPONSIBILITES

The purpose of SREC in reviewing all proposed research in Sunway Medical Centre is to safeguard the dignity, rights, safety and well-being of all actual or potential research subjects. SREC strives to ensure that all research is conducted in accordance with the International Conference of Harmonisation (ICH) (1996) and Malaysian Guidelines for Good Clinical Practice (GCP) (2004). SREC holds two-monthly meetings or a specially arranged meeting to review applications and notifies the applicant of the decision in writing within 45 days of receiving a complete submission.

1. TYPES OF RESEARCH THAT NEED ETHICAL REVIEW

All research conducted on human participants (Sunway Medical Centre patients) are reviewed by SREC. This includes research on pharmaceuticals, medical devices, medical radiation and imaging, surgical procedures, medical records, and biological samples, as well as epidemiological, social and psychological investigations.

2. APPLICATION FOR SREC ETHICAL REVIEW

All research to be conducted in Sunway Medical Centre will need to apply for SREC approval. In the case of those who have applied to the MREC/Monash, approval from these bodies is acceptable with the proviso that issues impacting Sunway Medical Centre or its patients be given due consideration. This would be done through an expedited review process by SREC.

All applications must be typewritten in English and submitted in hard copy by a qualified researcher (principal investigator) who is responsible for the ethical and scientific conduct of the research. Applications submitted by a corresponding person on behalf of the principal investigator must be initialized by the principal investigator. Please note that the Malaysian Guidelines for GCP requires that the investigators have approved and certified training in GCP.

2.1. APPLICATION FORMS

Application forms are available from the Secretary of SREC at:

SREC Secretariat
c/o SunMed Clinical Research Centre,
Sunway Medical Centre,
No. 5 Jalan Lagoon Selatan,
Bandar Sunway,
47500 Petaling Jaya, Selangor.
Tel: 03-8601 1079 Fax: 8601 1069

Electronic copies of forms are available upon request.

2.2. APPLICATION FEE

A one-off application fee of RM 1,000 per research project is charged for the services of SREC to review industry sponsored research. It is the prerogative of SREC to waive this fee for investigator-initiated research, which does not receive funding (non-commercial trials). No further fees are charged for reviewing applications for amendments to already SREC-approved research projects or for review of progress, serious adverse event and closure reports.

2.3. APPLICATION CLOSING DATES

The closing date for properly submitted (documents complete and valid) to be reviewed by SREC in the same month is the first Friday of each month. Proper submissions received after the closing date will be reviewed in the following month. For applications that may undergo expedited review, closing dates do not apply.

All applications received by SREC are stamped with 'date received…' and assigned a unique identification number. A copy of the first page of the application form or cover letter stamped with SREC official stamp represents a SREC acknowledgement of receipt for that application. This acknowledgement of receipt is sent out within 1 week of application receipt.

Upon receipt, submissions are checked for completeness and validity. If a document has been omitted by an applicant, this must be specifically justified. If the application is incomplete and thus invalid, the applicant will be informed of the deficiencies within one week from date received by SREC. The review period starts upon determination that the submission is complete and valid only.

In instances where SREC requires additional information or changes to documents from the applicant, the applicant shall respond within 8 weeks from the date of the notification letter, unless otherwise stated. After this dateline, the application file will be closed and a new application will need to be submitted again.

3. TYPES OF APPLICATIONS

There are 2 types of applications for ethical review by SREC. Those involving new research projects in humans (Research Approval Application) and those that involve changes to research projects already SREC-approved research projects involving humans (Research Amendment Application).

3.1. HOW TO APPLY FOR SREC APPROVAL TO CONDUCT NEW RESEARCH

Applicants for SREC approval to conduct a new research are required to fill the 'Research Approval Application Form' (Form 1). The supporting documents required for submitting this type of application can be found in the 'Research Approval Application Checklist' (Checklist 1). These supporting documents together with Form 1 and Checklist 1 are to be submitted in at least 3 copies (1 original and 2 photocopies). Payment of application fee of RM1,000 made out to SunMed – CRC Account is to be submitted together with these documents unless a fee waiver has been granted.

3.2. HOW TO APPLY FOR SREC APPROVAL FOR AMENDMENT(S) TO PREVIOUSLY SREC-APPROVED RESEARCH

During the conduct of the research, the investigator should provide to SREC all proposed amendments to be made to the research or research documents (outlined in Checklist 2). No deviations from, or changes of, the protocol should be initiated without prior written SREC approval, except *where necessary to eliminate immediate hazards* to the subjects or when the change(s) involves only logistical or administrative aspects of the research (e.g. change of monitor, telephone number).

For amendments (other than administrative and logistical ones), the applicant should submit documentation required for a thorough and complete review of ethics of proposed amendments.

This includes the submission of 'Research Amendment Application Form' (Form 2) and the proposed amendments and /or the study document(s) with proposed amendments clearly indicated and the reason for the amendment(s).

For amendments that *may* affect subject safety, rights or welfare, 3 copies (1 original and 2 photocopies) of the documents stated above are to be submitted to the Secretariat for review at a SREC meeting.

For amendments that clearly do not affect subject safety, rights or welfare, only 1 original copy of the documents stated above is to be submitted to the Secretariat. These applications may undergo an expedited review. However, if upon initial review, the proposed amendment is deemed by SREC as adversely affecting subject safety, rights or welfare; then another 2 copies will be required as this application would need to undergo a meeting review by all members of SREC.

For amendments that involve logistical or administrative aspects of the research, one copy of such amendment(s) accompanied by a cover letter will suffice, as such amendments are sent to SREC more for information rather than for ethical review. Form 2 need not be submitted.

**When in doubt as to whether an amendment may adversely affect subject safety, rights or welfare, please seek advice from the Secretariat.*

4. APPLICATION REVIEW & DECISION MAKING OF SREC

There are two types of review conducted by SREC. A *full review* is one that is conducted through a quadrate meeting of SREC members while the *expedited review* involves only the SREC chairperson, vice-chairperson and the secretary of SREC or the external review officer.

Applications to conduct new research projects involving humans are subjected to full review unless they involve research of minimal risk. For applications to amend an already SREC-approved research project, these may be subjected to a full review or expedited review. Amendments which may reduce the safety, rights, or welfare of subjects will undergo SREC meeting review. Only amendments which do not affect or which increase safety, rights, or welfare of subjects, or research with minimal risk are eligible for expedited review.

SREC holds its monthly meetings approximately two-weeks after the closing date of applications. When an application is reviewed in a scheduled SREC meeting (full review), the investigator or sponsor may be invited to provide information on any aspects of the research. Applicants will be notified of this meeting at least seven days in advance by the Secretariat. Independent consultants may also be invited to the meeting or to provide written comments, subject to applicable confidentiality agreements. However, these persons do not participate in the decision-making of SREC.

5. COMMUNICATING A DECISION OF SREC

The decision of SREC may be one of the following:

- Full Approval / favorable opinion
- Conditional Approval / modifications required prior to its approval / favorable opinion with reasons
- Disapproval / rejection / negative opinion with reasons
- Termination / suspension of prior approval /favorable opinions with reasons

For all applications reviewed by SREC, either through SREC meeting or in an expedited review, SREC shall document its opinion in writing on the SREC Decision Notification Form within 14 days from the review. SREC may append advice that is non-binding. However, all advice that is given as condition for approval are binding and a full written approval will not be issued until the applicant satisfies SREC that the conditions have been fulfilled.

6. SREC APPROVAL VALIDITY

Approvals for conduct of new research projects from SREC are valid for 18 months from the date of issue of the SREC Decision Notification Form. Any research project commencing after that date will need to be re-submitted to SREC as a new application.

7. SREC GUIDELINES, FORMS AND CHECKLISTS

The following Guidelines, Forms and Checklists are available at the Secretariat:

- Guidelines: SREC Application Guidelines
- Form 1: Research Approval Application Form
- Form 2: Research Amendment Application Form
- Form 3: Serious Adverse Event Report Form
- Form 4: Research Progress Report Form
- Form 5: Research Closure Report Form
- Checklist 1: Research Approval Application Checklist
- Checklist 2: Informed Consent Form & Written Subject Information Checklist
- Checklist 3: Genetic Research Checklist

8. WHAT DOES SREC LOOK FOR IN THE ETHICAL REVIEW OF AN APPLICATION?

Scientific Design and Conduct of the Study

1. The appropriateness of the study design in relation to the objectives of the study, the statistical methodology (including sample size calculations), and the potential for reaching sound conclusions with the smallest number of subjects.
2. The justification of predictable risks and inconveniences weighed against the anticipated benefits for the subjects and the concerned communities
3. The justification for the use of control arms
4. Criteria for prematurely withdrawing subjects
5. Criteria for suspending or terminating the research as a whole
6. The adequacy of provisions made for monitoring and auditing the conduct of the research, including the constitution of a data safety monitoring board (DSMB)
7. The adequacy of the site, including the supporting staff, available facilities, and emergency procedures
8. The manner in which the results of the research will be reported and published.

Recruitment of Subjects

1. The characteristics of the population from which the subjects will be drawn (including gender, age, literacy, culture, economic status, and ethnicity)
2. The means by which initial contact and recruitment is to be conducted
3. The means by which full information is to be conveyed to potential subjects or their representatives
4. Inclusion criteria for subjects
5. Exclusion criteria for subjects.

Care and Protection of Subjects

1. The suitability of the investigator(s)'s qualifications and experience for the proposed study.
2. At least one member of the investigator's team who will be conducting the study is GCP-certified or trained.
3. Any plans to withdraw or withhold standard therapies for the purpose of the research, and the justification for such action.
4. The medical care to be provided to subjects during and after the course of the research.
5. The adequacy of medical supervision and psychosocial support for the subjects.
6. Steps to be taken if subjects voluntarily withdraw during the course of the research
7. The criteria for extended access to, the emergency use of, and/or the compassionate use of study products.
8. The arrangements, if appropriate, for informing the subject's general practitioner (family doctor), including procedures for seeking the subject's consent to do so.
9. A description of any plans to make the study product available to the subjects following the research.
10. A description of any financial costs to subjects.
11. The rewards and compensations for subjects (including money, services, and/ or gifts).
12. The provisions for compensation/treatment in the case of the injury/disability/death of subjects attributable to participation in the research.
13. Review both the amount and method of payment to subjects to assure that neither presents problems of coercion or undue influence on the trial subjects. Payment to a subject should be prorated and not wholly contingent on completion of the trial by the subject
14. The insurance and indemnity arrangements

Protection of Subject Confidentiality

1. A description of the persons who will have access to personal data of the subjects, including medical records and biological samples.
2. The measures taken to ensure the confidentiality and security of personal information concerning subjects.

Informed Consent Process

1. A full description of the process for obtaining informed consent, including the identification of those responsible for obtaining consent.
2. The adequacy, completeness, and understandability of written and oral information to be given to the subjects, and when appropriate, their legally acceptable representative(s).
3. Clear justification for the intention to include in the research individuals who cannot consent, and a full account of the arrangements for obtaining consent or authorization for the participation of such individuals.
4. Assurance that subjects will receive information that becomes available during the course of the research relevant to their participation (including their rights, safety, and well-being)
5. The provisions made for receiving and responding to queries and complaints from subjects or their representatives during the course of a research project.
6. That information given to subjects in the informed consent or subject information is in accordance with the Malaysian Guidelines for Good Clinical Practice section 4.8.10. (Refer to Checklist 2 : Informed Consent Form and Written Subject Information)
7. When the protocol indicates that prior consent of the subject or subject's legally acceptable representative is not possible, the SREC should determine that the proposed protocol and/or other document(s) adequately addresses relevant ethical concerns and meets applicable regulatory requirements for such trials (i.e. in emergency situations)
8. When a non-therapeutic trial is to be carried out with the consent of the subject's legally acceptable representative, SREC should determine that the proposed protocol and/or other document(s) adequately addresses relevant ethical concerns and meets applicable regulatory requirements for such trials

Community Considerations

1. The impact and relevance of the research on the local community and on the concerned communities from which the subjects are drawn.
2. The steps taken to consult with the concerned communities during the course of designing the research. The influence of the community on the consent of individuals.
3. Proposed community consultation during the course of the research.
4. The extent to which the research contributes to capacity building, such as the enhancement of local healthcare, research, and the ability to respond to public health needs.
5. A description of the availability and affordability of any successful study product to the concerned communities following the research
6. The manner in which the results of the research will be made available to the subjects and the concerned communities.