Standard Operating Procedure of SAHAVAGI-Institutional Review Board

(SAHAVAGI-IRB)

1 Role of SAHAVAGI-IRB

The role of SAHAVAGI-IRB is to protect the dignity, rights, safety and well-being of all actual or potential research participants who are serving as the subjects of that research and ensure that animals if used for research, are treated humanely.SAHAVAGI- IRB should ensure the full review and evaluation of all ethical aspects of research proposals it receives prior to any research being carried out in field and/or laboratory settings, according to national ethical guidelines. The SAHAVAGI-IRB should be independent, competent and should timely review proposals. Moreover, it must be free from bias and not be under political, institutional, professional, business or any other influence. SAHAVAGI-IRB has rights to modify the proposed protocols, and timely monitor the research activities conducted post approval. It can disapprove proposals, suspend or stop any research that violates any ethical standards.

Guidelines to be followed by SAHAVAGI-IRB are:

National Ethical Guidelines for Health Research in Nepal and Standard Operating Procedures, published by National Health Research Council, 2011

National Health Care Waste Management Guidelines, 2002

2. Specific duties of board team

Duties of SAHAVAGI-IRB Members

The main essence of being an IRB member is to maintain its reputation of being fair, unbiased, impartial, and not being subjected to institutions administration pressures, external researchers, board members, political parties, study investigators, or any other professional, business or nonprofessional elements.

All the affiliated and non-affiliated members are expected to deliver their input to review research protocols on their best knowledge of legal an ethical issues and discuss issues and research from that perspectives.

Nonscientific members are expected to provide input on the areas that best fit to their knowledge, experience, and expertisein order to protect rights and welfare of the subjects. If under a circumstances their knowledge experience and expertise are insufficient to assess the research proposals and protocols, they can recommend IRB to take additional expertise.

Scientific members are expected to contribute to the evaluation of a study on its scientific and statistical merits and standards of practice. Additionally, these members may also advise the IRB in a nonscientific area to assess if the research proposal adequately protects the rights and welfare of subjects.

IRB members should attend at least 50% of scheduled IRB meetings and participate in IRB discussions of protocols.

Duties of IRB Chair

Conduct meetings of the IRB and order the members to produce proposal review report subjected to discussion during meetings. Meetings may be regular or urgent depending on case by case basis.

When required, Chair can expedite the review process.

Designating any responsibilities as appropriate to members. Any such designation is documented in writing and maintained by the IRB Administrative Staff or IRB Staff.

Providing leadership and guidance to the IRB.

Reviewing minor deviations and/or other events that qualify for review by expedited procedures.

Assist in annual evaluation of the IRB.

Ensuring that there are no conflict of interest present on the discussion. If present, conduct a voting on the research where conflict is present.

Conducting review of IRB minutes.

Selecting new IRB members.

3. SAHAVAGI-IRB membership

IRB is not comprised of members who represent only a single profession.

At least one member has primary concerns in scientific areas.

At least one member has primary concerns in nonscientific area.

At least one member is not otherwise affiliated with the organization and who is not part of the immediate family of a person who is affiliated with SAHAVAGI.

At least one member represents the perspective of research participants.

Member must not be convicted by a court of law for a criminal offence

Chairperson can be affiliated or nonaffiliated to SAHAVAGI.

At least 33% of the member must be female.

The Chairperson of Executive board of SAHAVAGI will appoint SAHAVAGI-IRB coordinator.

The executive committee (EC) members of SAHAVAGI-IRB will be appointed by the board chair in consultation with SAHAVAGI-IRB coordinator.

The tenure of SAHAVAGI-IRB EC will be for a period of 3 years.

Member Secretary will be fixed by the first meeting of SAHAVAGI-IRB.

SAHAVAGI-IRB EC comprises of one chairperson with at least 7 members. EC composition represents multidisciplinary team of various academic background.

A member who does not want to continue as member of the SAHAVAGI–IRB, he/she can submit resignation to IRB chair.

Membership on the IRB will cease when resignation is accepted by the SAHAVAGI–IRB chair.

Replacement of the vacant membership can be initiated through the upcoming SAHAVAGI–IRB meeting.

For any voluntary resignation a prior notice of at least one month should be given to IRB administrator.

The membership will automatically expire if the member:

- Is continuously absent in the meeting for more than 3 times without prior notice or failed to attend 50% of the scheduled meetings in a year.

- Deviates from the norms and standards of the committee.

- Non-compliance or resignation from the position.

4. Meeting of the SAHAVAGI-IRB

The meetings of the SAHAVAGI-IRB will be held on scheduled dates that will be announced in advance. IRB administrator will inform member secretary based on the applications received and member secretary will inform SAHAVAGI-IRB EC. The Member Secretary of IRB with the permission of the Chairman of the IRB will announce the meeting date.

Meeting will be chaired by chairperson. If chairperson has declared the conflict of interest, that meeting will be chaired by the eldest member who is present on that meeting.

The followings are considered as applicable for an IRB meeting:

The meeting of IRB will be planned inaccordance with the workloads and number of proposals received for review.

IRB members will be informed about the meeting at least 72 hours prior to the scheduled date

If felt necessary by the IRB, the applicant researcher or sponsor of the research can be invited to present the proposal or elaborate on specific issues of the proposal. Similarly, if necessary, experts can also be invited to the meeting for expert opinion about the research

Minutes will be kept of all decisions and procedures of the meeting

All the members and invitees present in the meeting should sign the minutes to indicate their presence.

Quorum requirement

The minimum number of members required to compose a quorum will be more than 51 percent of the total.

Invited experts will not be considered for quorum requirement.

At least one female member must be present in the meeting

At least one legal or non-affiliated member must be present in the meeting.

5. Administration of SAHAVAGI-IRB

Office of the IRB

SAHAVAGI central office will assign space within its building for the exclusive use by Chairman or the members of IRB and administration staff.

SAHAVAGI-IRB will have its own phone, fax, photocopy cupboard and administrative staff (one full time IRB administrator and a part- time financial staff- not compulsorily from EC).

Fund management

It will have its own fund management process and fund disbursement mechanism. Revenue will be generated through research proposals registration and review process. An institutional overhead charge of up to 5% of SAHAVAGI-IRB ethical review process charge can be levied on researches involving human subjects and animals. Each proposal submitted to SAHAVAGI-IRB will be charged for ethical review process as per the SAHAVAGI-IRB rule. External donationscould also be the source of revenue. Generated fund will be utilized but not limited to conduct of meetings, salary to the IRB admin personnel’s, monitoring and evaluation of research. Financial accounts will be subjected to annual audit under the SAHAVAGI audit system.

Documentation and Archiving

A Single file will be created for each proposal that is submitted to the SAHAVAGI-IRB. All documentation and communication of IRB will be dated, filed, and archived in locked key board maintaining confidentiality. IRB administrator will be responsible for that. The documents will be archived for a minimum period of 5 years following the completion of a study.

Documents that should be filed and archived include but not limited to:

The Constitution, written standard operating procedures of the SAHAVAGI-IRB, and regular (annual) reports.

The curriculum vitae of all IRB members.

A list of all members, reviewers and experts.

A record of all income and expenses of the SAHAVAGI-IRB.

The published guidelines for submission established by the IRB.

The agenda of the IRB meetings.

The minutes of the IRB meetings.

All materials submitted by an applicant.

The correspondence by IRB members with applicants or concerned parties regarding application, decision, and follow‐up.

A copy of the decision and any advice or requirements sent to an applicant.

All written documentation received during the follow‐up.

The notification of the completion, premature suspension, or premature termination of a study.

The final summary or final report of the study.

6. Ethical clearance application process

Any researchers, who want to do study/data collection/research in/behalf of/collaboration with SAHAVAGI, must get ethical clearance from SAHAVAGI-IRB. Collaborating partners getting ethical approval from other external or their own internal review boards are exempted from this provision. However they must submit the copy of evidence of ethical approval.

- Application Submission: The principal investigator (PI)/CO-PI and/or correspondent researcher should submit an application form on behalf of whole research team in a given standard format. Application should be addressed to member secretary of SAHAVAGI-IRB.Application form can be located atsahavagi.org.np

- Language of Applications: All Applications must be submitted in English.

- Application should include one hard copy and an electronic copy of the proposal along with the application processing fees. Application fees information will be provided by IRB administrator.

- Only those applications fulfilling the requirements will be accepted for review.

- Deficits in the application shall be informed to the applicants within one weeks of submission.

- Incomplete applications will have to be resubmitted.

- A receipt of the accepted application will be provided to the research representative.

- SAHAVAGI-IRB can request the applicant for the additional documents to the proposal during the review that will be informed to the applicant.

- Application should include the Informed Consent Form as a separate copy which is to be used while undertaking the research. In addition, this may include a translation copy, in a local language if that is applicable.

Documents required for the ethical clearance application

Filled application form with signature and date in SAHAVAGI-IRB format.

Latest version of curriculum vitae of principal investigator and co-investigators with academic qualification and work experiences.

The protocol of the proposed research with the supporting documents. (A copy of valid and reliable research tools, questionnaires etc)

A copy of informed consent form should be included in the application. This should include a detail description of the process of giving the information to the research participant and its content, process of obtaining the consent, the person responsible for obtaining the informed consent and documentation of the signature of the researcher/research participant and /witness if applicable.

A signed statement by the researcher stating that he or she will abide by the ethical principles of research.

Submission of all the necessary documents: All the documents mentioned above must be submitted to IRB administrator in SAHAVAGI-IRB office.

Processing time:Application will be processed for review within 20 working days. The application will not be pending for more than 20 days except in special circumstances.

7. Elements of the Review Process

After verifying the documents needed for the research proposal, IRB administrator will submitit to the general secretary of SAHAVAGI-IRB.

General Secretary will allocate the reviewer/s for each proposal depending upon the subject of expertise. The reviewer/s can either be a member of SAHAVAGI-IRB or an expert identified from outside SAHAVAGI-IRB member.

After reviewing the proposal, the reviewer/s will submit it to the Administrative Officer with written comments attached in a separate page.

Some of the minor reviews can pass reviewer and approved without convening a meeting of the SAHAVAGI-IRB.For this approval, member secretary will review the comments and protocols and proposal in brief and sign on behalf of SAHAVAGI-IRB for approval.

For proposal requiring board discussion, administrative Officer will take it to the SAHAVAGI-IRB EC.

Reviewer will brief about the research proposal. (If reviewer is from outside the IRB member, Member secretary of IRB will brief about the research proposal).

For further clarification, the committee can invite the researcher to present the proposal to the panel of experts and its members. This will help the committee to understand the proposal in a better way and guide the researcher appropriately.

The proposal will be discussed in full board IRB meeting for ethical review. SAHAVAGI-IRB EC will decide on the acceptance of the paper for research.

8. Decision making

The IRB will make the decision only if the meeting has met required quorum. Decision can be any of the following:

Approved: either with or without comments or questions addressed to the applicant; any replies to a committee’s comments or questions to be forwarded in due course.

Approved subject to conditions: subject to recommended revisions of the proposal and/or satisfactory answers to questions asked of the applicant. The applicant’s reply and/or revised proposal will be forwarded to consider the revisions that have been made and to provide final approval.

Approval deferred: pending substantial revisions of the proposal/study and/or satisfactory answers to questions asked of the applicant. The applicant’s reply and/or revised proposal will be forwarded to the committee for reconsideration and final approval.

Approval declined: reasons for declining approval to be forwarded to the applicant, either with or without an invitation to submit a substantially revised protocol for reconsideration.

- Normally the decision will be taken by consensus, (if consensus is not possible then a vote will be taken)

- The IRB member should withdraw from the decision process when conflict of interests arises; the member should declare the conflict of interest.

- The IRB may approve the proposal conditionally with specific suggestions to the researcher.

- The negative decision on a proposal should be supported by clearly stated reasons.

If the applicant is the committee member, he/she can participate in the committee member but he will not have voting right in that particular agenda.

On behalf of the IRB, the Administrative officer will communicate its decision to the applicants in writing withinone week after the meeting.

All letter related to ethical clearance will be issued with signature of member secretary. If member Secretary has declared the conflict of interest, that letter will be sign by the other member who is identified by the committee. This member will also serve as delegated role of general secretary in his absence.

Other administrative letter will be issued by the administrative officer with coordination with the general secretary. Approval will be given for maximum of three years at a time.

9. Elements of Post approval

Projects, which have not been commenced within two years of original approval, must be resubmitted to SAHAVAGI-IRB.

If the project is not complete within three years’ validation period, the researcher will be required to write to SAHAVAGI-IRB to request an extension of approval.

When the SAHAVAGI-IRB is feels the circumstances have arisen such that a research project is not being or cannot be conducted in accordance with the approved protocol and that, as a result, the welfare and rights of participants are not or will not be protected, the IRB will take the following steps:

- Withdraw approval.

- Recommend that the research project be discontinued, suspended, or that other necessary steps be taken.

- A research must not continue if ethical approval has been withdrawn and the researches didn’t comply with any special conditions required by the SAHAVAGI-IRB.

Monitoring and Review of research activities

SAHAVAGI-IRB will establish a monitoring procedure for following the progress of studies for which ethical clearance is received from the time the decision was taken until the completion of research.

The review intervals will be determined by the nature and the events of research projects, though each protocol should undergo a review at least once a year.

A decision of a review will be issued and communicated to the applicant, indicating a modification, suspension, or termination of IRB’s original decision or confirmation that the decision is still valid.

In the case of the premature suspension/termination of a research, the applicant should notify the SAHAVAGI-IRB of the reasons for suspension/termination; a summary of results obtained in a study prematurely suspended/terminated should be submitted to the SAHAVAGI-IRB.

The applicant will submit progress reports as per IRBs decision.

The applicant will inform the SAHAVAGI-IRB at the time of the completion of a study.

The applicant will submit to the SAHAVAGI-IRB a copy of the final summary or final report of a study.

The IRB can issue an approval letter for publication as per need.

10. Right to Appeal/Complaint

An investigator who receives an unfavorable review by the committee has the right of appeal. This appeal is initiated by filing a notice of appeal in writing to the Head of SAHAVAGI within thirty (30) days from the date of notice he/she received.

TheHead may request the SAHAVAGI-IRB for re-review of the proposal if he/she gets an appeal for the same.

The SAHAVAGI-IRB shall notify the investigator for rehearing, and the investigator shall have the right to appear at the rehearing to defend the proposal.

Any research participants involved in a research project has the right to voice complaints or concerns directly to the member secretary of IRB.

In case of an appeal to the committee by a research participant, the committee will determine the validity of the complaint and notify the principal investigator of its judgment in the matter. The latter will abide by the decision of the committee.

11. Revision of SOP This SOP document is subjected to continuous change, review and update according to SAHAVAGI-IRB decisionconsidering changing national and internal context and legal situations or required improvements in the system.