**Constitution and Terms of Reference**

of the Research Ethics Committee

Colegio San Agustin – Bacolod

Adopted on: [Day/Month/Year]

**I. Name**

The name of the committee shall be Colegio San Agustin – Bacolod Research Ethics Committee (CSA-B REC).

**II. Aims**

The aims of the committee shall be to ensure that research projects of Colegio San Agustin – Bacolod involving human participants adhere to high ethical standards to promote the safety and welfare of research participants.(to include operational definition of terms).

**III. Powers**

In order to achieve its aims the committee shall:

a. Safeguard the rights, safety, and well-being of research participants with

special attention to vulnerable population taking into account the interests,

needs of the researchers, and having due regard for the requirements of

relevant regulatory agencies and applicable laws

b. Evaluate the conduct of research in Colegio San Agustin - Bacolod in

accordance with international and national guidelines, local laws, standards of

professional conduct and practice, and community morals, values, customs,

traditions and needs.

c. Promote research integrity by identifying and resolving conflicts of interests.

d. Report to the institutional or national authorities any matter that affects the

conduct and ethics of research which in its view may affect the rights and

safety of research participants.

e. Observe a systematic and organized documentation of all protocol and process

related documents including actions taken and other pertinent information.

f. Submit an annual report to the Philippine Health Research Ethics Board

(PHREB) through DOST-PCHRD which includes the following:

* Composition of the REC, including a short CV and term of office of each member
* Members of the REC secretariat, office and email addresses, and contact numbers;
* Number of meetings held during the year, including the date and venue;
* Number of researches reviewed by the REC

**IV. Membership**

1. Those who are part of the CSA-B REC shall include individuals who had training in Basic Research Ethics Review conducted by the Philippine Health Research Ethics Board (PHREB).
2. It shall be multi-sectoral with eight (8) individuals with adequate representation of members with regard to sex and age.
3. It shall have one member whose primary are of interest is in a non-scientific area (layperson) and at least one who can represent the interests and concerns of the community and it values.
4. It shall have one member who is independent of the institution or the research site (non-affiliated member).
5. There shall be at least five (5) alternate members; of the aforementioned, there should be at least one (1) alternate member for the layperson, one who represents the concerns of the community and for the non-affiliated member.
6. Every individual that comprise the CSA-B REC shall have one vote during regular or special meetings.
7. Every individual that comprise the CSA-B REC shall be bound to a confidentiality agreement and disclosure of conflict of interest.
8. Membership of the CSA-B REC covers one academic year and may be renewed depending on its performance.

**V. Management**

1. The committee shall be managed by the REC Chairperson
2. The officers of the committee shall be the REC Chairperson and the REC Member Secretary.
3. The committee shall function in a manner that adheres to its recent Standard Operating Procedures Manual.
4. The committee shall meet on a quarterly basis, at least four (4) times a year, on the 3rd Friday of the month.
5. The REC Chairperson shall chair all meetings of the committee except during instances whereby a conflict of interest in the protocols for review exists.
6. The quorum for the committee shall be fifty (50) percent plus one (1).
7. Voting during committee meetings shall be by show of hands. If there is a tied vote then the REC Chairperson shall be given a second vote.
8. During times where, for any valid reason deemed by the REC Chairperson, a member of the committee may not be able to attend in a meeting, alternate members may fill in the vacancy provided that it does not exceed eight (8) individuals that comprise the committee and that the absentee member is not a reviewer of any protocol whether during instances of expedited or full board review.

**VI. Duties of REC Constituents**

1. REC Chairperson

* Presides over committee meetings except for instances where there is conflict of interest.
* Organize REC meetings
* Signs on behalf of the committee regarding protocol and process related decisions and communications.
* Prepares and submits the annual report of the committee to be submitted to the Research and Planning Office, Office of the President and the Philippine Health Research Ethics Board (upon level 1 accreditation) before May of every year.
* Represents the committee in any inter-office meetings that will require the involvement of the committee.
* Prepares the REC Budget and recommends qualified individuals for its membership.
* Inform REC members and personnel about training workshops and arrange for the latter’s participation in such workshops through Faculty and Employees Development Program.
* Declare any conflict of interest in general and for specific protocols for review
* Organize the preparation, review, revision, and distribution of SOPs and guidelines

1. REC Member Secretary

* Prepare and distribute protocol files for review, oversee protocols reviewed by respective primary reviewers and together with the REC Chairperson assign primary reviewers to review protocols submitted to
* Prepare and maintain meeting agenda and minutes and ensure the accuracy of the aforementioned
* Organize an effective and efficient tracking procedure for each protocol or process related document received
* Maintain the REC Active Files and Archives, Communication logs, References and other document files, especially their security and confidentiality
* Supervise the preparation of communication pertinent to protocol-review and process related actions to the research proponent
* Inform research proponents regarding REC application processes
* Declare any conflict of interest in general and for specific protocols for review
* Manage the REC Office under the supervision of the REC Chair
* Perform other REC-related tasks that may be assigned to him/her by the REC Chair

1. REC Member

* Make a timely and thorough review and decision regarding protocols given to him/her for evaluation
* Familiarize him/herself with the SOPs of the REC, his/her terms of reference, and the international and national guidelines on research ethics
* Participate actively in the REC meetings. It is expected that a member will have at least 80% attendance during the period of appointment because attendance is integral to the effectiveness of the REC as a review board
* Recommend appropriate action on protocol deviations and violations which led to untoward incidents based on monitoring reports
* Participate in the review of the progress reports, final reports, and other amendments presented during the REC meeting
* Participate in Site Visits and similar activities as needed
* Maintain confidentiality of the documents and deliberations of REC meetings
* Declare any conflict of interest in general and for specific protocols for review
* Submit an updated and signed CV at the start of each calendar year
* Refer to the REC Chair any suggestion, complaint, or grievance of research participants, research proponents, and/or sponsors before acting on them and after consulting REC members
* Participate in required REC related training with proof of attendance in such training activity submitted to the REC Member Secretary

**VII. Resources and Budget**

1. The REC Chairperson in coordination with the committee members prepares the committee budget which will lay down the funds that it needs for operations. The aforementioned budget is expected to be consistent with the guidelines provided by the Budget Office of the school.
2. Committee expenditures shall be liquidated accordingly following the guidelines provided by the Office of the Vice President for Finance and Administration.
3. As an institutional policy, all funds required for training shall be coursed through the Office of the Human Resource Management and Development via the Faculty and Employees Development Program (FEDEP) of the school.
4. The committee shall be provided with an office to which regular and special meetings will be held and files, protocol or process related, will be kept, secured and archived.

**VIII. Meetings**

1. The committee shall have its regular meetings quarterly on the 3rd Friday of the month.
2. All constituents of the committee shall be given at least two (2) weeks’ notice of the meeting and shall be entitled to attend and vote. The quorum for meetings shall be fifty (50) percent plus one.
3. The notice of the meeting shall include the date, time, venue, and flow of the REC meeting together with its corresponding agenda.
4. The agenda of the meeting shall include the presentation and approval of the provisional agenda, declaration of conflict of interest, reading and approval of the minutes of the previous meeting, business arising from the minutes of the previous meeting, new business, review of protocols and protocol related documents for full review, report of results of expedited review and deliberation on REC operations related matters.
5. Special meetings shall be held for review of requests from external researchers as approved by the School President. Furthermore, special meetings shall also be held to address urgent matters as decided by the REC Chairperson.

**IX. Relationships to other Units**

1. The committee is an independent body in terms of the scientific and ethical review of submitted research protocols; its decision over the aforementioned is absolute and shall be acknowledged accordingly by the educative community.
2. It provides technical support to the Research and Planning Office in ensuring that research projects within the school adhere to high ethical standards thus contributory to realizing the school’s vision.
3. It shall attend and address queries and complaints regarding the conduct of the research projects which it has previously reviewed.
4. It coordinates with the ad hoc committee (Research and Planning Director, Human Resource Director and Quality Assurance Director) tasked with addressing complaints made regarding REC operations. Coordination with the aforementioned is expected to effectively address valid complaints to further improve the quality of the services that the REC provides.
5. It submits annual report on reviewed research protocols to the Research and Planning Office and the Office of the School President. Furthermore, it annually submits the same to the Philippine Health Research Ethics Board as noted by the Research and Planning Director and the School President upon having been granted with level 1 accreditation.

**X. Alterations to the Constitution and Terms of Reference**

Any changes to this constitution must be agreed by at least eight (80) percent of the constituents of the REC upon voting during a regular meeting.

This constitution was adopted during an assembly of the REC on \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

Signed by:

REC Chairperson: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

REC Member Secretary: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

REC Member: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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