



INSTITUTIONAL REVIEW BOARD

I. Saint Paul's Hospital Iloilo: History, Vision, Mission and Organizational Chart

HISTORY:

The solicitude for the sick of the late Msgr. Dennis J. Dougherty of Philadelphia, who was then Bishop of Jaro, was the original motivating force that brought about the foundation of St. Paul's Hospital of Iloilo. As early as 1909 he asked the Sisters of St. Paul of Chartres, who were just starting their work in the Philippines, to establish a hospital in Iloilo.


It was not until February 15, 1911 when four pioneer sisters, Mother Marie Donatien, Sister Antoine du Sacre Coeur, Sister Augustine De Marie and Sister Felix de Marie came and answered the clergy. Their first convent was a former warehouse of the Ynchausti Y Compania on Calle Rosario. Two adjacent residential homes were made the seats of the hospital where they were to establish. Three more nuns, Sister Marie Scholastique, Sister Marie Estelle and Sister Adrien joined them some months later. The latter was formally installed as the first superior of the establishment. On May 20 of the same year, their doors open to the sick. Dr. Samuel Carson of the Philippine Railway brought in the first patient.

This was followed by Drs. Gilchrist, Kilayko and Arroyo. Dr. Carson became the first Medical Director and was pioneer doctor succeeded by Dr. Arroyo who held the position up to the outbreak of World War II. These generous French Religious pioneers made rapid adjustment to their new environment. They endeared themselves to the Ilonggos who fondly called them "Madres de San Pablo".

After two years of hard work, they found it necessary to expand their accommodations for the sick who sought their care. Msgr. Dougherty followed closely the progress of the hospital with enthusiasm. In 1913 he went back to his native States to secure funds for putting up the hospital. The project was placed under the patronage of the little flower whose beautification was under study. In less than a year's time, the bishop came back with the needed funds.

Bishops Foley and Mc. Closky carried on the work because the founder was recalled to become Bishop of Buffalo and later Cardinal of Philadelphia. The hospital building was completed and formally occupied in 1916. Msgr. Dougherty never lost his interest, however, in the growing institution up to his death in 1951. Recognizing the dedicated services of the Sisters, he turned over to them full ownership and administration in a written statement executed in 1941.

Today, St. Paul's Hospital Iloilo is a tertiary level training general hospital with a capacity of 265 beds. It caters to the health needs of the inhabitants of Iloilo City, its neighboring towns and provinces like Aklan, Antique, Capiz, Palawan and Negros Occidental. The Hospital has been counted as one of the best hospitals and received both local and national awards for its cleanliness and quality services.

	INSTITUTIONAL REVIEW BOARD
	I. Saint Paul's Hospital Iloilo: History, Vision, Mission and Organizational Chart

VISION:

We envision St. Paul's Hospital of Iloilo, Inc. as a Christ-centered, excellent, innovative, global healthcare and training hospital.

MISSION:

We commit ourselves to:

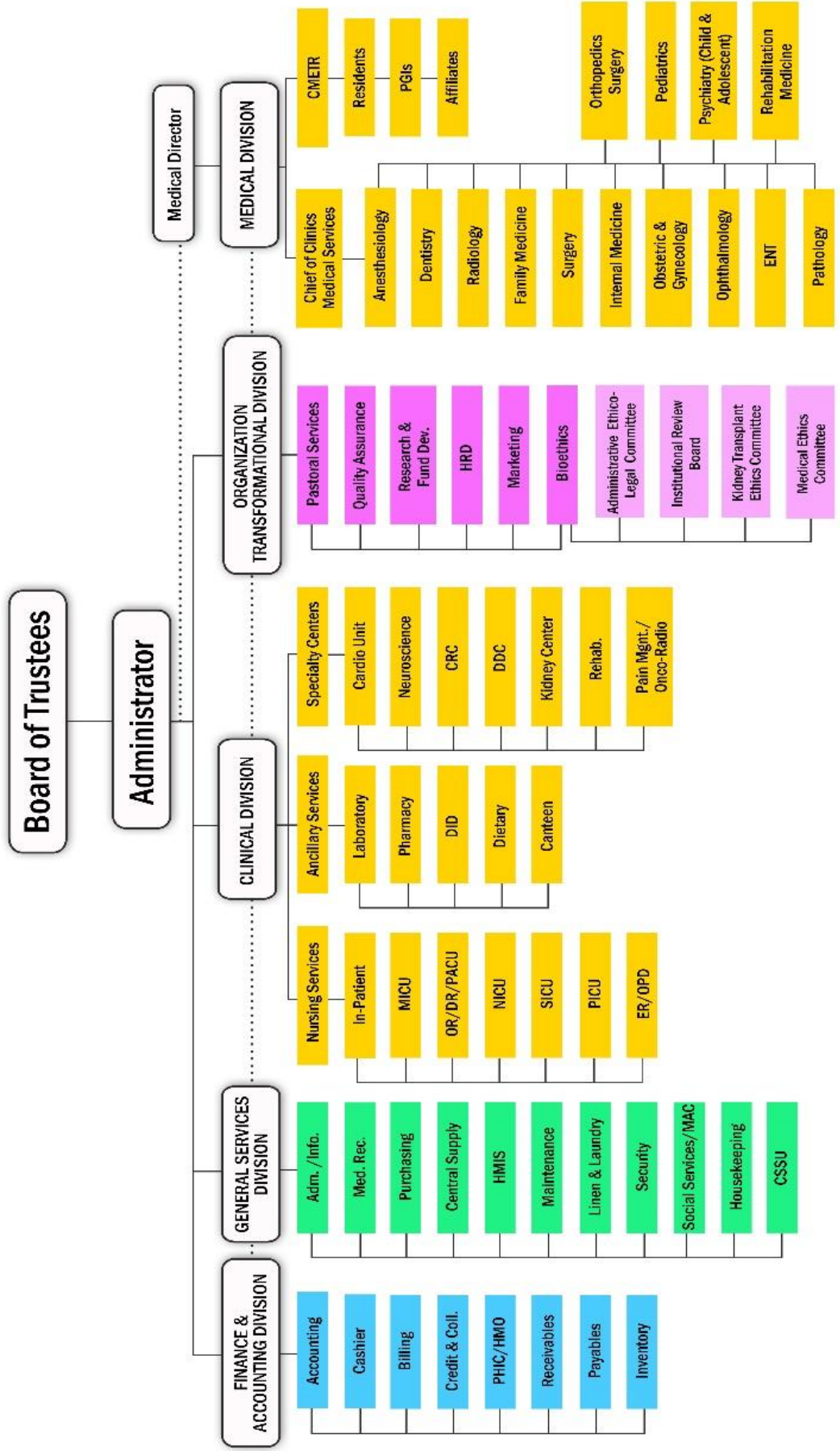
1. Offer Christ-centered excellent healthcare upholding the bioethical principles and the teaching of the Catholic Church;
2. Innovate & develop competencies of health care professionals through continuing relevant training and research programs;
3. Continually implement and sustain operational and financial excellence through Christian stewardship & good governance.

CORE VALUES: C-A-R-E

1. **Compassion** – capacity and readiness to suffer with those who suffer; to feel one with the suffering and those in pain, to be moved with one's deepest interiority "may pagmamalasakit".
2. **Accountability** – the capacity and readiness to accept consequences of one's decision/action and the responsibility of stewardship in caring and serving.
3. **Respect** – showing appreciation towards the value of another person; manifest a differential regard to the values; principles and beliefs of others.
4. **Excellence** – doing the right thing all the time; error free state; quality of doing things efficiently.



ST. PAUL'S HOSPITAL OF ILOILO, INC FUNCTIONAL ORGANIZATIONAL CHART





INSTITUTIONAL REVIEW BOARD

II. SPHI IRB: History, Vision, Mission and Organizational Chart

HISTORY:

In 1996, St. Paul's Hospital Iloilo Ethics Committee was constituted. This was the beginning of Bioethics Committee. It was on June 27, 2006 that the Ethics Committee revised their existing policies and guidelines for the comprehensive and efficient review of researches that involved human participants. In cases of research and experimentation involving human subjects, the Committee made sure that the Clinical researches conform to the moral and scientific principles that justify the research. The participants were well-informed of the Study. Informed consents were signed, the subjects were free to terminate the study on any stage and for whatever reason and that the clinical research followed the national and international guidelines for the protection of the safety and well-being of the participants.

On November 1, 2007, the name of Ethics Committee was changed to St. Paul's Hospital Ethics Review Board (IERB). The following were the composition of the said Committee: Chairman - Fr. Paul Solomia (Priest); Co-Chair - Dr. Jaime Manila (Medical Doctor); Secretary - Joy Braza (Registered Nurse); Members - Sr. Donatilla Torres, SPC (Pharmacist), Atty. Luisito Hofileña (Lawyer), Dr. Levy Suyo (Medical Doctor), and Ms. Jemmayma Maybay (Lay).

In 2008, Ms. Joy Braza, the IERB Secretary, was replaced by Ms. Joan Marie Chiu, also a Registered Nurse. In January 2011, the Administrator re-appointed Fr. Paul Solomia as Chair of the IERB, Ms. Joan Marie Chiu as Secretary, Sr. Donatilla Torres, Dr. Levy Suyo, and Ms. Jemmayma Maybay as IERB Members. Atty. Jose Mari Benjamin Tirol was appointed as a new member.

It was in August 2013 that Sr. Rosamond Marie Abadesco, SPC, Administrator, hired Ms Eden Shiz Parpa as a Part-time staff for the Office. In November of that same year, she assumed fulltime responsibility as Office Secretary to manage documents for the function of the IERB in regulating Ethical Practices among the already existing /on-going Clinical trial groups.

On July 15, 2013, Sr. Rosamond Marie Abadesco, SPC appointed new members for the Committee. The compositions were: Chairman- Dr. Levy Suyo; Secretary- Eden Shiz Parpa; Members- Msgr. Paul Solomia, Dr. Jaime Manila, Maria Thelma Servidad, Sr. Rowena Rodil, SPC, and Atty. Jose Mari Benjamin Tirol.

In July 2014, the Administrator appointed Sr. Henrietta Esmero, SPC as a new member to replace Sr. Rowena Rodil, SPC who received a new assignment in Luzon. The Administrator also changed the name of St. Paul's Hospital Ethics Review Board to Institutional Review Board Committee.

On February 27, 2015, Philippine Health Research Ethics Board released a memorandum addressing all the Ethics Review Committees to submit application for Accreditation in order to review clinical trials research protocols of drugs and devices for FDA registration. On April 30 of 2015, SPHI submitted an application for Level 3



INSTITUTIONAL REVIEW BOARD

II. SPHI IRB: History, Vision, Mission and Organizational Chart

Accreditation to the Philippines Health Research Ethics Board. This move was an evidence of SPH's commitment to submit to International and National Standard practices pertaining to the conduct of all types of researches.

In June 2015, the IRB, in preparation for the visit of the PHREB Accreditors ventured to adapt the DOH Template on Standards Operating Procedures and in August 18, 2015, the new SOP version was approved by the Administration. It was at the same month that she appointed Dr. Jaime Manila as Chair of the Board after the end of the term of Dr. Levy Suyo.

The other members of the organized committee are: Dr. Rowena Cosca (Psychiatrist), Sr. Henrietta Esmero, (SPC Sister; Nurse), Maria Thelma Servidad (Businesswoman), Atty. Jose Mari Benjamin Tirol (Lawyer), Msgr. Paul Solomia (Priest) and Ms Eden Shiz Parpa, (Registered Nurse). The Administrator also changed the name of Institutional Review Board Committee to Institutional Review Board. Following the reorganization of the IRB, Sr. Maria Kristina Bergonia, SPC took over the management of the Office after the resignation of Ms Eden Shiz Parpa.

On October 24, 2015 the Administrator appointed Dr. Ma. Cecilia Divinagracia Florete (Gastroenterologist), Dr. Venerio Gasataya, Jr. (Surgeon) and Mr. Christopher Tabsing (School Principal), as new members of the board. Likewise, Dr. Ma. Cecilia Divinagracia Florete was appointed Member-Secretary. On November 9, 2015 Msgr. Paul Solomia ended his term. With grateful hearts, the Administration and the IRB thanked Msgr. Paul for his commitment and dedication to the service of the IRB. On the same month, the Administrator hired Ms. Queenie Macalalag as clerk secretary to be with Sr. Maria Kristina Brrgonia, SPC in the IRB.

Then on February 17-19, 2016 the IRB of St. Paul's Hospital was visited by the Philippine Health Research Ethics Board (PHREB) for accreditation. One month after the accreditation/survey visit of PHREB, the final report of the visit was sent. The IRB immediately acted upon the recommendations of PHREB. Thus, on March 29, 2016 during the IRB monthly meeting a plan of action was made and it was immediately sent to PHREB. Meanwhile, the Administrator upon the suggestion of the IRB, appointed Independent Consultants of different specialty for a period of two years from April 1, 2016 to April 1, 2018. The appointment of the IRB members were changed into staggered term to ensure the continuity of the IRB work.

Another major recommendation of PHREB was to revise the IRB SOP. Thus, an IRB SOP Team was created during the regular IRB meeting, composed of IRB members, to review/revise the IRB SOP according to the suggested format of PHREB. On May 20, 2016, the SOP version 02 was approved by the Administrator. The revised SOP together with the other documents were sent to PHREB for approval.

On May 13, 2016 the administrator appointed Sr. Joselina R. Bonono, SPC to replace Sr. Ma. Kristina Bergonia, SPC who received a new assignment in Luzon.



INSTITUTIONAL REVIEW BOARD

II. SPHI IRB: History, Vision, Mission and Organizational Chart

On August 9, 2016 the Philippine National Health Research System & Philippine Health Research Ethics Board awarded a provisional certificate of Accreditation Level III to SPHI IRB for one year.

Another recommendation from PHREB is to revise the IRB SOP according to the suggested format of PHREB. On January 2017, the SOP version 3 was approved by the Administrator. The revise SOP together with other documents were send to PHREB for approval.

On May 2017, the Administrator re-appointed Mr. Christopher Tabsing and Dr. Venerio Gasataya Jr. as members of the IRB.

On August 9, 2017, the Philippine National Health Research System & Philippine Health Research Ethics Board awarded the certificate of Accreditation Level III to SPHI IRB for two years.

On August 10, 2017 the Administrator appointed Sr. Edith Christine Aguirre, (SPC Sister; Nurse) as the new member to replace Sr. Henrietta Esmero, SPC who received a new assignment in Mindanao.

On April 2018, the administrator re-appointed the Independent Consultant and Dr. Aimee Lourdes Ponje was added to the group.

On May 19, 2018 Sister Ma. Jessica Formacion, (SPC Sister; Nurse) was appointed as the new member by the administrator to replace Sr. Edith Christine Aguirre, SPC who received also a new assignment in Mindanao. The hospital Administrator renewed the appointment of Dr. Venerio Gasataya Jr., Dr. Ma. Cecilia Florete, Mr. Tabsing and Mrs. Maria Thelma Servidad.

On October 2018, SPHI IRB submitted an application form for Level III Re-accreditation to Philippine Health Research Ethics Board. This move was an evidence of SPHI continued commitment to submit to International and National Standard Practices pertaining to the conduct of all types of researches. Thus, the SOP version 04 was approved by the Administrator. The revised SOP together with the other documents needed for re-accreditation were sent to PHREB for perusal and approval.

On March 12-15, the Philippine Health Research Ethics Board visited the SPHI-IRB for re-accreditation.

On March 25, 2019, the IRB received the Accreditation visit Final Report from the accreditors.

On June 2019, the Administrator appointed a statistician, non-affiliated in the person of Mrs. Ma. Romy Alexis Consulta as the new member of the IRB as per accreditor's requirements. The IRB SOP 5th Edition was also approved on the same month.



INSTITUTIONAL REVIEW BOARD

II. SPHI IRB: History, Vision, Mission and Organizational Chart

On September 2019, The Philippine Health Research Ethics Board (PHREB) has granted one (1)-year Level 3 Accreditation for SPHI- IRB.

On December 30, 2019, SPHI-IRB SOP 7th Edition was approved by the Hospital Administrator.

August 2020, Sr. Joselina Bonono, SPC (IRB Office Manager) was transferred to other assignment. Sr. Ma. Jessica Formacion, SPC was appointed by the Hospital Administrator to be the new IRB Office Manager.

On January 13, 2021, SPHI-IRB granted two (2)-year Level 3 Accreditation by PHREB.

April 2021, Sr. Ma. Jessica Formacion, SPC was assigned as Nursing Service Supervisor and she focused only as IRB Member. New IRB Office Manager was appointed by the Hospital Administrator in the person of Sr. Gertrude Caryls Kuebler, SPC.

On June 2021, Mr. Christopher Tabsing was a non-affiliated member as he was transferred to another school.

On June 2022, Sr. Gertrude Caryls Kuebler, SPC was appointed by Hospital Administrator as IRB office Manager after Sr. Jessica Formacion, SPC was assigned to her new assignment.

SPHI IRB GUIDING PRINCIPLES IN THE ETHICAL EVALUATION OF RESEARCHES:

The St. Paul's Hospital of Iloilo IRB is guided in its reflection, advice, and decision by the ethical principles and procedures expressed in the following international guidelines and documents such as the Declaration of Helsinki (2013), CIOMS (2009). The IRB functions in accordance with national laws, regulations, and guidelines and provides its own standard operating procedures based on Operational Guidelines for Ethics Committees That Review Biomedical Research (2000) by the World Health Organization (WHO); Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants (2011) by the World Health Organization (WHO); International Conference on the Harmonization of Good Clinical Practice (ICH-GCP); National Ethical Guidelines for Health Research (2011) by the Philippine Health Research Ethics Board (PHREB) and Philippine Food and Drug Authority regulations and other relevant laws and regulations. It also takes the initiative to be informed, as appropriate, by national/local ethics committees and researchers of the impact of the research that it has approved.

GENERAL ETHICAL PRINCIPLES: (Based on CIOMS 2002)

All research involving human subjects should be conducted in accordance with three basic ethical principles, namely respect for persons, beneficence and justice. It is generally agreed that these principles, w/c in the abstract have equal moral force, guide the



INSTITUTIONAL REVIEW BOARD

II. SPHI IRB: History, Vision, Mission and Organizational Chart

conscientious preparation of proposals for scientific studies. In varying circumstances they may be expressed differently and given different moral weight, and their application may lead to different decisions or courses of action. The present guidelines are directed at the application of these principles to research involving human subjects.

Respect for persons incorporates at least two fundamental ethical considerations, namely:

- a. Respect for autonomy, which requires that those who are capable of deliberation about their personal choices should be treated with respect for their capacity for self-determination; and
- b. Protection of persons with impaired or diminished autonomy, which requires that those who are dependent or vulnerable be afforded security against harm or abuse.

Beneficence refers to the ethical obligation to maximize benefit and to minimize harm. This principle gives rise to norms requiring that the risks of research be reasonable in the light of the expected benefits, that the research design be sound, and that the investigation be competent both to conduct the research and to safeguard the welfare of the research subjects. Beneficence further proscribes the deliberate infliction of harm on persons; this aspect of beneficence is sometimes expressed as a separate principle, *non-maleficence* (do no harm)

Justice refers to the ethical obligation to treat each person in accordance with what is morally right and proper, to give each person what is due to him or her. In the ethics of research involving human subjects the principle refers primarily to *distributive justice*, which requires the equitable distribution of both the burdens and the benefits of participation in research. Differences in distribution of burdens and benefits are justifiable only if they are based on morally relevant distinctions between persons: one such distinction is vulnerability. "Vulnerability" refers to a substantial incapacity to protect one's own interests owing to such impediments as lack of capability to give informed consent, lack of alternative means of obtaining medical care or other expensive necessities, or being a junior or subordinate member of a hierarchical group. Accordingly, special provision must be made for the protection of the rights and welfare of vulnerable persons.

Sponsors of research or investigators cannot, in general, be held accountable for unjust conditions where the research is conducted, but they must refrain from practices that they are likely to worsen unjust conditions or contribute to new inequities. Neither should they take advantage of the relative inability of low-resources countries or vulnerable population to protect their own interests, by conducting research inexpensively and avoiding complex regulatory system of industrialized countries in order to develop products for the lucrative markets of those countries.

In general, the research project should leave low-resources countries or communities better off than previously or, at least, no worse off. It should be responsive to their health needs and priorities in that any product developed is made reasonably available to them, and as far as possible leave the population in a better position to obtain effective health care and protect its own health.



INSTITUTIONAL REVIEW BOARD

II. SPHI IRB: History, Vision, Mission and Organizational Chart

Justice requires also that the research be responsive to the health conditions or needs of vulnerable subjects. The subjects selected be the least vulnerable necessary to accomplish the purposes of the research. Risk to vulnerable subjects is most easily justified when it arises from interventions or procedures that hold out for them the prospect of direct health-related benefit. Risk that does not hold out such prospect must be justified by the anticipated benefit to the population of which the individual research subjects is representative.

Ethical Principle for Medical research Involving Human Subjects (Based on DECLARATION OF HELSINKI 2013)

1. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.

The Declaration is intended to be read as a whole and each of its constituent paragraphs should be applied with consideration of all other relevant paragraphs.

2. Consistent with the mandate of the WMA, the Declaration is addressed primarily to physicians. The WMA encourages others who are involved in medical research involving human subjects to adopt these principles.

General Principles

3. The Declaration of Geneva of the WMA binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act in the patient's best interest when providing medical care."
4. It is the duty of the physician to promote and safeguard the health, well-being and rights of patients, including those who are involved in medical research. The physician's knowledge and conscience are dedicated to the fulfilment of this duty.
5. Medical progress is based on research that ultimately must include studies involving human subjects.
6. The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Even the best proven interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.
7. Medical research is subject to ethical standards that promote and ensure respect for all human subjects and protect their health and rights.



INSTITUTIONAL REVIEW BOARD

II. SPHI IRB: History, Vision, Mission and Organizational Chart

8. While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.
9. It is the duty of physicians who are involved in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects. The responsibility for the protection of research subjects must always rest with the physician or other health care professionals and never with the research subjects, even though they have given consent.
10. Physicians must consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration.
11. Medical research should be conducted in a manner that minimizes possible harm to the environment.
12. Medical research involving human subjects must be conducted only by individuals with the appropriate ethics and scientific education, training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional.
13. Groups that are underrepresented in medical research should be provided appropriate access to participation in research.
14. Physicians who combine medical research with medical care should involve their patients in research only to the extent that this is justified by its potential preventive, diagnostic or therapeutic value and if the physician has good reason to believe that participation in the research study will not adversely affect the health of the patients who serve as research subjects.
15. Appropriate compensation and treatment for subjects who are harmed as a result of participating in research must be ensured

VISION:

A Christ-centered accredited board for ethical review and monitoring of researches.

MISSION:

1. Receive and evaluate research proposals as to adherence to accepted ethical principles.
2. Assure that evaluation is based on local, national and international guidelines.
3. Update members on latest national and international guidelines.



INSTITUTIONAL REVIEW BOARD

II. SPHI IRB: History, Vision, Mission and Organizational Chart

