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INTRODUCTION

Ethical Framework of Philippine Children's Medical Center Institutional Research - Ethics Committee (PCMC IR-EC)

The **Philippine Children's Medical Center Institutional Research – Ethics Committee (PCMC IR-EC)** is guided in its reflection, advice, and decision by the following elements of research ethics –

1) social value
2) informed consent
3) vulnerability of research participants
4) risks, benefits and safety
5) privacy and confidentiality of information
6) justice
7) transparency

Specifically, the PCMC IR-EC shall adhere to the following principles, values, and key procedures in the conduct of research ethics review:

- The participation of human beings in research can only be justified if the study has social value. Social value refers to the relevance of the study to an existing social or health problem such that the results are expected to bring about a better understanding of related issues, or contribute to the promotion of well-being of individuals, their families, and communities.
- The study design, methodology, and data collection, overall, should be able to generate information supportive of the objectives of the study. Social value can only be realized if the study is scientifically valid.
- Informed consent is a decision of a competent potential participant to be involved in research after receiving and understanding relevant information, without having been subjected to coercion, undue influence, or inducement.
- For all research involving humans, the researcher shall obtain the voluntary informed consent of the prospective research participant.
- In obtaining informed consent, sponsors and researchers shall have the duty to avoid deception, undue influence, or intimidation.
- Vulnerable participants shall require special protection because of certain characteristics or situations that render them as such. Vulnerable participants are those who are relatively or absolutely incapable of deciding for themselves whether or not to participate in a study for reasons such as physical and mental disabilities, poverty, asymmetric power relations, and marginalization, among others and who are at greater

risk for some harms.

- Research is justified if there is a reasonable likelihood that the population from which the participants are derived stand to benefit from the research.
- All research involving human participants shall be preceded by a careful assessment of predictable risks, burdens, and foreseeable benefits to the research participant or to others.
- Every precaution shall be taken to minimize the negative impact of the study on the research participant's wellbeing.
- Research shall be conducted only if there is an acceptable positive benefit-risk ratio.
- Researchers shall adhere to the principles of transparency, legitimate purpose, and proportionality in the collection, retention, and processing of personal information (Data Privacy Act of 2012).
- Researchers must respect participants' right to privacy. Unless required by law, the confidentiality of information shall at all times be observed. Records that link individuals to specific information shall not be released. This requirement shall be included in the informed consent form.
- Researchers shall refrain from identifying individuals or groups when release of information about them can expose them to possible harm or social stigma unless required by law.
- In research involving human participants the principle of justice refers primarily to distributive justice, which requires the equitable distribution of both the burdens and the benefits of participation in research. That is, it should not be the case that one group in society bears the costs of research while another group reaps its benefits. Research should not worsen existing health and social inequities.
- Ethical research shall be characterized by transparency. It is imperative for all parties to be transparent about matters relating to their involvement. Transparency is not diametrically opposed to privacy. On the contrary, transparency is an element of ethical research that promotes confidence in the research enterprise, even when privacy and anonymity need to be preserved about sensitive matters. The need for transparency also entails disclosure of research results.
- Researchers must be transparent about aspects of a study that may have an impact on the rights, health, and safety of participants, or in respect to information that may have a bearing on the decision of participants to give or withhold their informed consent.
- Transparency imposes responsibilities on researchers to disclose information about their affiliations, financial interests, or other loyalties that may affect their objectivity and the integrity of their research output.

Source: National Ethical Guideline for Health and Health-Related Research (NEGHHRR 2017)

The PCMC IR-EC is guided by the ethical principles and procedures as expressed in the following international guidelines:

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- Declaration of Helsinki (2013 and subsequent revisions)
- International Conference on the Harmonization of Good Clinical Practice (ICH-GCP)
- CIOMS 2016
- Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants (2011) by the World Health Organization (WHO)

The PCMC IR-EC will function in accordance with national laws, regulations, and guidelines.

- National Ethical Guidelines for Health and Health-Related Research (NEGHHRR 2017) by the Philippine Health Research Ethics Board (PHREB)
- Data Privacy Act of 2012
- DOH AO 2017-0021 on Single Joint Research Ethics Board (SJREB)
- FDA AO 2018-0002 on Medical Device
- Administrative Orders from DOH, Philippine FDA and other relevant agencies

The PCMC IR-EC adopts its own standard operating procedures based on:

- Operational Guidelines for Ethics Committees That Review Biomedical Research (2000) by the World Health Organization (WHO)
- DOH-REC SOP Template
- FERCAP SOP Templates
- PHREB SOP Workbook
- Standard Operating Procedures for Single Joint Research Ethics Board (SJREB)

The PCMC IR-EC adheres to national and international ethical standards and recognizes that the protocols it approves may have undergone review and approved by other ethics committees including the Single Joint Research Ethics Board (SJREB) prior to their implementation in specific sites.

In evaluating protocols and ethical issues, the PCMC IR-EC is cognizant of the diversity of laws, cultures and practices governing health research in various local sites/countries around the world.

It attempts to inform itself, whenever possible, of the regulations and requirements of sponsor countries conducting global protocols in the Philippines; and of the requirements and conditions of various localities where a proposed PCMC research is being considered.

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The PCMC IR-EC will take the initiative to be informed, as appropriate, by current state-of-the-art researches and publications of the impact of the research that it has approved.