1. **Policy Statement**

The**Cebu Institute of Medicine and Cebu Velez General Hospital CIM-CVGH IRB** was established to provide guidance to the 2 institutions **Cebu Institute of Medicine and Cebu Velez General Hospital** in the conduct of human research. The IRB anchors its guidelines on both national and international standards including but not limited to the Declaration of Helsinki, Belmont Principle, CIOMS, Good clinical Practice.

1. **Objective**

This SOP aims to ensure that the conduct of human subject research in the Cebu Institute of Medicine and Cebu Velez General Hospital are done in accordance with national and International guidelines on human subjects Research. The Primary objective of this policy is to safeguard the rights, welfare and wellbeing of the human subjects under research within the jurisdiction of the 2 institutions.

1. **Scope:**

This Policy applies to all faculty, students, staff, residents and consultants conducting or planning to conduct human Subjects Research in CIM-CVGH. Principal Investigators outside of CIM-CVGH may also submit proposals for review by the CIM-CVGH IRB.

1. **Responsibilities**

The CIM-CVGH IRB is responsible for the acceptanc,e review, approval and continuing review of proposals on human subjects research submitted to the CIM-CVGH IRB.

1. **Definition**

**Human Subject** means a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

1. **Workflow (Refer to Pertinent SOPs that follows)**
2. **Forms:**

**None**

1. **History:**

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| ***Version No.*** | ***Date*** | ***Authors*** | ***Main Change*** |
| *1* | *April 10, 2016* |  | *First Draft* |

1. **References:**
* Philippine Health Research Ethics Board (PHREB) Workbook 2015
* World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
* International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
* National Ethical Guidelines for Health Research 2011 PNHRS
* Belmont Report
* Declaration of Helsinki
* Federal Policy for the Protection of Human Subjects2018