PHILIPPINE CANCER SOCIETY

MANILA CANCER REGISTRY

STANDARD OPERATING PROCEDURES

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Philippine Cancer Society

1. SCOPE AND PURPOSE

1.1 Purpose

This Standard Operating Procedure (SOP) establishes the policies, processes, governance framework, and quality standards governing the operations of the Philippine Cancer Society – Manila Cancer Registry (PCS–MCR) as a Population-Based Cancer Registry (PBCR).

The SOP defines the methodology for systematic collection, abstraction, coding, validation, analysis, storage, protection, and dissemination of cancer incidence data for all eligible cases occurring among residents within the defined catchment area of PCS–MCR. It ensures that registry operations are conducted in accordance with:

- Republic Act No. 11215 (National Integrated Cancer Control Act) and its Implementing Rules and Regulations
- Republic Act No. 10173 (Data Privacy Act of 2012)
- Commonwealth Act No. 3573 (Law on Reporting of Communicable and Notifiable Diseases)
- Relevant Department of Health Circulars recognizing and authorizing Population-Based Cancer Registries
- International standards issued by the International Agency for Research on Cancer (IARC) and the International Association of Cancer Registries (IACR)

This SOP is designed to ensure that cancer registration activities meet internationally accepted standards for completeness, validity, comparability, and reproducibility of data (IARC, 2013; IARC, 2014). This SOP adopts and operationalizes the standards set forth in the normative references listed in Section 2. Where conflicts arise, the more stringent standard shall apply.

This SOP functions as a controlled operational standard for PCS–MCR. It defines the end-to-end registration lifecycle, the required decision rules, control points, documentation outputs, and approval authorities that ensure registry activities are consistent, auditable, and aligned with both national policy requirements and IARC/IACR standards.

The intended outcome of this SOP is a registry dataset that is complete, valid, comparable, and reproducible for surveillance, reporting, and approved research use.

1.2 Scope of Application

This SOP applies to all PCS–MCR personnel and designated collaborators involved in any stage of the cancer registration lifecycle, from retrospective case ascertainment through analytical dataset finalization, reporting, and data governance.

The SOP covers all reportable malignant neoplasms and other tumors included under national and international cancer registration standards within the defined catchment area of PCS–MCR.

This document governs registry operations regardless of the software platform used for data capture or storage. While data systems may evolve over time, the methodological standards, coding principles, data quality controls, and confidentiality safeguards described herein shall remain constant.

1.2.1 Process Boundaries

PCS–MCR processes include: retrospective case ascertainment; data collection from multiple sources; record linkage and consolidation; abstraction; coding and classification; validation and quality checks; statistical analysis and reporting; analytical dataset finalization; controlled data release; and record retention and archiving.

PCS–MCR does not provide clinical care, does not alter medical records, and does not replace the clinical diagnosis process.

The registry's operational scope is case-based surveillance and reporting. Patient follow-up is not routinely conducted as a registry function, except when required for approved research or validation activities.

1.2.2 Interfaces and External Parties

The registry interfaces with reporting facilities and data sources for case ascertainment, including hospitals, diagnostic units, pathology laboratories, and Local Civil Registry Offices.

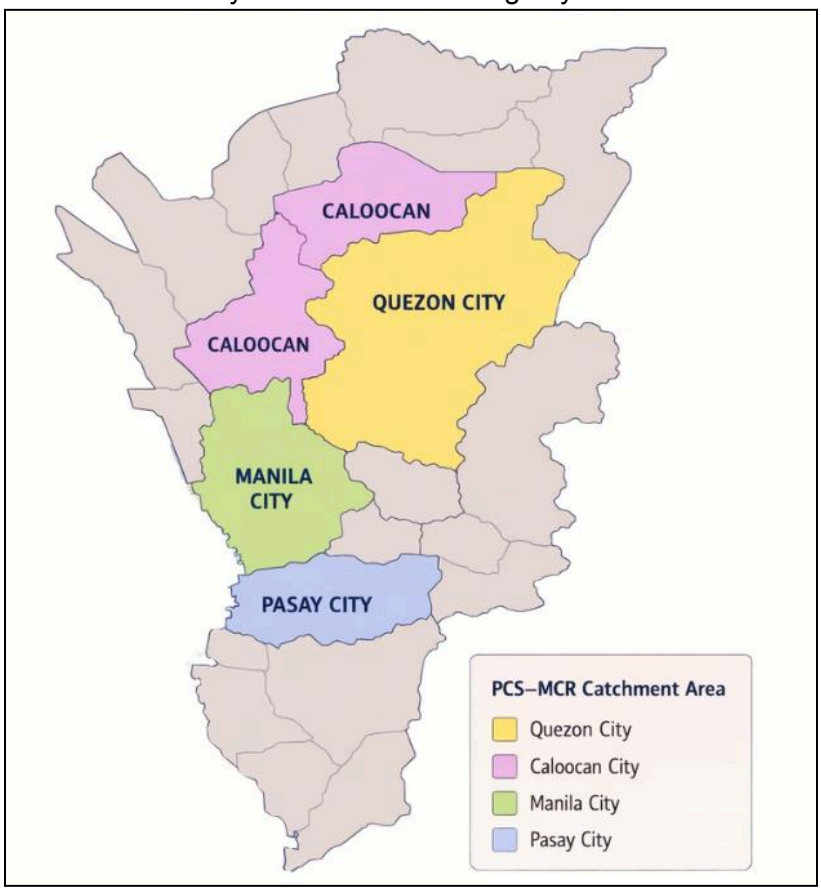
The registry interfaces with national and international bodies for cancer surveillance and benchmarking, including the Department of Health and IARC-coordinated reporting mechanisms.

Data sharing with other PBCRs occurs under controlled rules defined in Section 9 and only after record linkage, consolidation, and residency determination.

1.3. Catchment Area and Coverage

PCS–MCR is a population-based cancer registry responsible for cancer surveillance among usual residents of its defined catchment area. The catchment area includes the following four cities: Caloocan City, Manila City, Pasay City, and Quezon City. This coverage is aligned with official population denominators for incidence rate calculations. Detailed residency rules and handling of conflicting addresses are defined in Section 6.

Figure 1. Philippine Cancer Society - Manila Cancer Registry Catchment Area



1.4 Platform Neutrality

This SOP is platform-agnostic. Registry software and data capture tools may evolve over time, but the registry's methodological requirements, decision rules, coding standards, validation controls, confidentiality safeguards, and approval authorities defined in this SOP remain binding regardless of the platform used.

1.5 Model SOP Positioning

While tailored to PCS–MCR operations, the structure and controls of this SOP reflect best practice requirements consistent with IARC/IACR guidance and may be used as a reference model for PBCR operations in the Philippines.

1.6. High-Level Process Overview

This SOP is supported by a formally controlled Process Map or Swimlane Diagram, which is maintained in the Document Management System (DMS) as a Level 3 document. This diagram visually details the end-to-end registration cycle, major handoffs between personnel roles, and the precise location of all critical control points referenced in this document.

Figure 1. Operational Workflow Diagram

2. NORMATIVE REFERENCES

This Standard Operating Procedure shall be implemented in accordance with the following national laws, regulatory issuances, and international technical standards. Where conflicts arise, applicable Philippine law shall prevail, while technical interpretation of cancer registration

methodology shall follow International Agency for Research on Cancer (IARC) and International Association of Cancer Registries (IACR) standards.

PCS–MCR shall maintain access to the most current versions of these references. Continued applicability shall be reviewed during scheduled SOP review and internal quality monitoring.

2.1 National Laws and Regulatory Issuances

- Congress of the Philippines. (2019). *Republic Act No. 11215: National Integrated Cancer Control Act*. Official Gazette of the Republic of the Philippines.
- Congress of the Philippines. (2012). *Republic Act No. 10173: Data Privacy Act of 2012*. Official Gazette of the Republic of the Philippines.
- Congress of the Philippines. (1939). *Commonwealth Act No. 3573: Law on Reporting of Communicable and Notifiable Diseases*. Official Gazette of the Republic of the Philippines.
- Department of Health. (2022). *Department Circular No. 2022-0292*. Conduct of Data Collection and Consolidation for the Philippine Population-Based Cancer Registry Under RA 11215. 27 May 2022.
- Department of Health. (2024). *Department Circular No. 2024-0306*. Conduct of Data Collection and Consolidation for the Philippine Population-Based Cancer Registry Under RA 11215. 8 July 2024.

2.2. International Standards and Technical Guidance

- Storm, H., Brewster, D. H., Coleman, M. P., Deapen, D., Oshima, A., Threlfall, T., & Démaert, E. (2005). Guidelines for confidentiality and cancer registration. *British Journal of Cancer, 92*, 2095–2096. https://doi.org/10.1038/sj.bjc.6602618
- Roshandel, G., Badar, F., Barchuk, A., Roder, D. M., Sangrajrang, S., Mery, L., Nobuyuki, H., Halimi, A., Mathur, P., Shrestha, G., & Mosavi Jarrahi, A. (2023). REPCAN: Guideline for reporting population-based cancer registry data. *Asian Pacific Journal of Cancer Prevention, 24*(9), 3297–3303.
- International Association of Cancer Registries (IACR) & International Agency for Research on Cancer (IARC). (2004). *Guidelines on confidentiality for population-based cancer registration*. IARC Internal Report No. 2004/03. Lyon: IARC.
- Piñeros, M., Parkin, D. M., & Brierley, J. (2024). *User's guide to Essential TNM (E TNM)* (Version 4.2). Lyon: IARC.
- Finesse, A. M., Somdyala, N., Chokunonga, E., & Parkin, D. M. (2024). *Standard procedure manual for population-based cancer registries in sub-Saharan Africa* (Version 5). African Cancer Registry Network. Oxford: Prama House.
- Bray, F., Znaor, A., Cueva, P., Korir, A., Swaminathan, R., Ullrich, A., Wang, S. A., & Parkin, D. M. (Eds.). (2014). *Planning and developing population-based cancer registration in low- and middle-income settings*. IARC Technical Publication No. 43. Lyon: IARC.

- Jensen, O. M., Parkin, D. M., MacLennan, R., Muir, C. S., & Skeet, R. G. (Eds.). (1991). *Cancer registration: Principles and methods*. IARC Scientific Publication No. 95. Lyon: IARC.
- European Network of Cancer Registries (ENCR) & International Agency for Research on Cancer (IARC). (2011). *Guidelines on confidentiality and ethics for population-based cancer registration and linked activities in Europe* (Version 3).
- Esteban, D., Whelan, S., Laudico, A., & Parkin, D. M. (1995). *Manual for cancer registry personnel*. IARC Technical Report No. 10. Lyon: IARC.
- Shambaugh, E. M., Weiss, M. A., Fritz, A., Hurst, M., Hahn Johnson, C., Kruse, M. A., & Seiffert, J. (1999). *SEER program self-instructional manual for cancer registries: Book 1 – Objectives and functions of cancer registries* (3rd ed.). NIH Publication No. 99-917. Bethesda, MD: National Cancer Institute.
- World Health Organization. (1976). *WHO handbook for standardized cancer registries*. Geneva: WHO.
- World Health Organization (WHO). (2013). International Classification of Diseases for Oncology, Third Edition (ICD-O-3), First Revision (or current revision as adopted by PCS-MCR).

2.3. Internal PCS-MCR Controlled Documents and Tools

- PCS–MCR Confidentiality Protocol
- PCS–MCR Data Release Request Form and supporting templates
- PCS–MCR data collection forms and field collection tools, including legacy paper forms and current digital collection structure
- PCS–MCR coding lists and internal codebooks used for standardized capture and classification

3. DEFINITION OF TERMS

For the purposes of this Standard Operating Procedure, the terms are defined in Table 1.

Table 1. Definition of Terms

Accuracy	The degree to which recorded data correctly reflect the information contained in the original source documents.
Active Case Finding / Case Ascertainment	A method of data collection in which registry personnel systematically visit or access health facilities, pathology laboratories, and other data sources to identify eligible cancer cases.
Age-Standardized Rate	A weighted average of age-specific rates, calculated using a standard reference population, to allow comparison of cancer rates across populations with different age structures.

Analytical Dataset Finalization Date	The date on which all consolidation, coding, quality review, and duplicate resolution activities for a defined reporting period are completed, and the dataset used for analysis and report generation is formally approved by the Registry Director. Subsequent updates to individual cases may occur in future cycles, but the published report reflects the dataset as finalized on that date.
Authorized Personnel	Individuals formally designated and granted role-based access to identifiable registry data in accordance with registry policies and data protection requirements.
Basis of Diagnosis	The most valid method by which the cancer diagnosis was established, coded according to internationally recognized classification standards.
Catchment Area	The clearly defined geographic area for which the registry is responsible for capturing all incident cancer cases among usual residents. The catchment area includes specified cities or municipalities and is aligned with official population denominators for incidence rate calculations.
Coding	The systematic assignment of standardized alphanumeric codes to cancer cases based on internationally accepted classification systems, including the International Classification of Diseases for Oncology (ICD-O) for topography and morphology, and other applicable staging or classification systems. Coding ensures comparability, consistency, and interoperability of registry data across institutions and countries.
Comparability	The degree to which registry data are consistent with national and international coding standards, allowing meaningful comparison across regions and over time.
Completeness	The extent to which all eligible cancer cases occurring within the catchment area are captured by the registry.
Confidentiality	The obligation to protect identifiable cancer registry data from unauthorized access, disclosure, or misuse, consistent with national data protection laws and international registry guidelines.
Confidentiality Agreement	A formal written undertaking signed by PCS–MCR personnel, consultants, trainees, or contractors prior to being granted access to identifiable registry data, affirming their obligation to protect sensitive personal information, restrict data use to authorized registry purposes, prevent unauthorized disclosure, and maintain confidentiality even after termination of employment or engagement.

Corrective Action	Action taken to eliminate the cause of a detected non-conformity or other undesirable situation; it is an action to prevent recurrence.
Data Controller	The natural or juridical person who determines the purposes and means of processing personal data. For purposes of this SOP, PCS–MCR acts as the data controller for registry data under its custody.
Data De-identification	The process of removing or masking direct personal identifiers to reduce the risk of re-identification before data release.
Data Privacy Officer (DPO)	The individual formally designated by the Philippine Cancer Society to oversee compliance with the Data Privacy Act of 2012 and related regulations. The DPO ensures that PCS–MCR data processing activities comply with legal, regulatory, and organizational data protection requirements, including risk assessment, breach response, data subject rights management, and oversight of confidentiality safeguards.
Data Processing Agreement	A formal written contract between PCS–MCR, as data controller, and an external data processor that governs the processing of personal data strictly on behalf of PCS–MCR. The agreement defines processing instructions, confidentiality obligations, security safeguards, breach notification requirements, and limitations on data use.
Data Processor	A natural or juridical person who processes personal data on behalf of PCS–MCR under documented instructions and without determining the purpose of processing.
Data Sharing Agreement	A formal written agreement between PCS–MCR and a data-providing institution that defines the purpose, scope, confidentiality safeguards, and permitted uses of shared cancer data.
De-identified Dataset	A dataset from which direct identifiers have been removed or masked and where reasonable measures have been applied to minimize risk of re-identification prior to external release.
Death Certificate Notification (DCN)	A cancer case initially identified through a death certificate indicating cancer as a cause of death, which triggers further investigation to confirm prior diagnosis and obtain diagnostic details.
Death Certificate Only (DCO) Case	A cancer case initially identified solely from a death certificate, with no prior record of diagnosis found in hospital or clinical sources at the time of identification.

Death Certificate Only Percentage (DCO%)	The proportion of registered cancer cases for which a death certificate is the sole source of information and no additional clinical or diagnostic details are available after trace-back.
Duplicate Case	Two or more records referring to the same primary cancer in the same individual, identified through record linkage or matching procedures.
Incidence Rate	The number of new cancer cases occurring in a defined population during a specified period, divided by the population at risk during the same period, typically expressed per 100,000 population. Incidence rates may be presented as crude rates or age-standardized rates using a standard reference population.
Incident Case	A newly diagnosed primary malignant neoplasm occurring in a resident of the catchment area within a defined calendar year, meeting established inclusion criteria for cancer registration.
Internal Audit	A systematic, independent, and documented process for obtaining evidence and evaluating it objectively to determine the extent to which the registry's operations, processes, and systems comply with the requirements of this SOP and other planned arrangements.
Morphologically Verified (MV) Case	A cancer case in which the diagnosis has been confirmed by cytology, hematology, histology of primary tumor, or histology of metastasis.
Morphologically Verified Percentage (MV%)	The proportion of registered cancer cases with diagnosis confirmed by cytology, histology of primary tumor, or histology of metastasis, expressed as a percentage of all incident cases.
Morphology	The histologic type and biologic behavior of a tumor, coded using ICD-O morphology codes.
Mortality Rate	The number of deaths due to cancer occurring in a defined population during a specified period, divided by the population at risk during the same period, typically expressed per 100,000 population. Mortality rates may be crude or age-standardized.
Multiple Primary Rules	Standardized criteria established by IARC/IACR and other recognized bodies for determining whether tumors in the same individual constitute separate primary cancers.
Multiple Primary Tumors	Two or more independent primary malignant tumors occurring in the same individual, determined according to internationally accepted multiple primary rules (IARC/IACR or other recognized standards adopted by PCS–MCR).

Non-Conformity	A non-fulfillment of a requirement of this SOP, a statutory/regulatory mandate, or an international standard. This triggers the Corrective Action process.
Observed Survival	The proportion of patients alive after a specified time following diagnosis, calculated without adjustment for background mortality.
Passive Reporting	A method of data collection in which healthcare institutions or data sources submit cancer case information directly to the registry without routine on-site abstraction.
Person-Years at Risk	The total time contributed by individuals in a population during which they are at risk of developing cancer or dying from cancer.
Population-Based Cancer Registry (PBCR)	An organized system for the systematic collection, storage, analysis, interpretation, and reporting of data on all reportable cancer cases occurring among residents of a defined catchment area within a specified time period.
Prevalence	The total number of existing cancer cases (both newly diagnosed and previously diagnosed) in a defined population at a specified point in time (point prevalence) or over a defined period (period prevalence), divided by the population at risk.
Primary Site (Topography)	The anatomical location where a malignant neoplasm originates, coded according to ICD-O topography classification.
Record Linkage (also referred to operationally as matching or cross-checking)	The systematic process of comparing and matching records from multiple data sources to determine whether they refer to the same individual or tumor, in order to eliminate duplicate entries and consolidate complete case information.
Registry Data Protection Focal Person	The designated PCS–MCR staff member responsible for implementing day-to-day data protection procedures within the registry, coordinating with the organizational Data Privacy Officer on compliance matters.
Relative Survival	The ratio of observed survival among cancer patients to the expected survival of a comparable group from the general population.
Reportable Neoplasm	A malignant tumor and other specified neoplasms included under national legislation and international cancer registration standards, coded according to the International Classification of Diseases for Oncology (ICD-O).
Reporting Facility	Any hospital, pathology laboratory, diagnostic center, clinic, or civil registry office within the defined catchment area from which cancer case information is obtained.

Residency Verification	The process of confirming that a cancer case meets the registry's residency criteria within the defined catchment area.
Survival Rate	The proportion of patients diagnosed with cancer who remain alive for a specified period after diagnosis. Survival may be expressed as overall survival, net survival, or relative survival depending on the analytic method used. Survival estimates require accurate follow-up and determination of vital status.
Timeliness	The interval between the date of cancer diagnosis and the date of entry into the registry database.
Trace-Back	The systematic process of reviewing hospital records, pathology reports, or other medical sources to verify and obtain diagnostic information for cases initially identified through death certificates.
Unique Registry Identifier	A registry-assigned identification number that uniquely identifies each registered cancer case within the PCS–MCR database.
Usual Resident	An individual whose primary place of residence is within the defined catchment area at the time of cancer diagnosis, regardless of where diagnosis or treatment occurred.
Validity	The accuracy and correctness of recorded data elements compared to source documentation.

These definitions are binding for interpretation of this SOP.

4. CONTEXT OF THE ORGANIZATION

4.1 Historical Background of Philippine Cancer Society - Manila Cancer Registry

Cancer surveillance in the Philippines predates Republic Act No. 11215. The Philippine Cancer Society's Central Tumor Registry of the Philippines was established in 1968 as one of the earliest organized cancer documentation initiatives in the country.

In 1983, pursuant to Ministry of Health directives mandating hospital cooperation in Metro Manila and Rizal, the registry was formally reorganized as a population-based cancer registry under the Philippine Cancer Society. This marked the transition from hospital-based tumor documentation to systematic, population-based cancer surveillance with defined geographic coverage, structured case ascertainment, and standardized data abstraction.

Since 1983, the Philippine Cancer Society – Manila Cancer Registry (PCS–MCR) has operated continuously as a population-based cancer registry, conducting retrospective active case

ascertainment, abstracting hospital and mortality records, and producing incidence statistics reflective of the cancer burden among usual residents of its defined catchment area.

The enactment of Republic Act No. 11215 institutionalized cancer registration under the National Cancer Registry and Monitoring System. PCS–MCR continues to operate within this statutory framework while maintaining methodological alignment with international standards issued by the International Agency for Research on Cancer (IARC), the International Association of Cancer Registries (IACR), and related technical guidance referenced in Section 2.

4.2 Legal Authority and Mandate

The operations of PCS–MCR are grounded in the following legal instruments:

- Commonwealth Act No. 3573, establishing mandatory reporting of notifiable diseases
  Republic Act No. 11215 (National Integrated Cancer Control Act) and its Implementing Rules and Regulations, mandating the establishment and strengthening of Population-Based Cancer Registries
- Republic Act No. 10173 (Data Privacy Act of 2012), governing the lawful processing and protection of personal information
- Department of Health Department Circular No. 2022-0292
- Department of Health Department Circular No. 2024-0306

Under these legal instruments, hospitals and health facilities are mandated to provide authorized cancer registrars access to medical records necessary for cancer surveillance. Data collected are treated with strict confidentiality and used exclusively for public health, epidemiologic, and cancer control purposes.

Pursuant to Republic Act No. 11215 and Commonwealth Act No. 3573, cancer reporting constitutes a mandatory public health function. Hospitals, diagnostic facilities, and other reporting entities within the catchment area are required to permit authorized registry personnel access to records necessary for cancer surveillance. The processing of identifiable cancer data by PCS–MCR is performed under lawful public health authority and does not require individual patient consent when conducted for surveillance purposes in accordance with national law.

Pursuant to Republic Act No. 10173 (Data Privacy Act of 2012), the Philippine Cancer Society designates a Data Privacy Officer (DPO) responsible for institutional oversight of data protection compliance. PCS–MCR operates under the institutional oversight of the designated Data Privacy Officer (DPO) and implements registry-specific technical, organizational, and physical safeguards in accordance with Republic Act No. 10173, IARC/IACR confidentiality guidance, and institutional privacy policies. All registry personnel are required to comply with institutional data protection policies and execute confidentiality agreements prior to accessing identifiable data.

4.3 Relationship with the National Cancer Registry System

PCS–MCR, as a recognized Population-Based Cancer Registry, operates in alignment with the goals of the National Integrated Cancer Control Act (RA 11215). While mandatory national reporting guidelines are currently under development, the registry is committed to the future integration of its data, including the quarterly or semi-annual submission to the National Cancer Registry System upon the effectivity of its mandated operational protocol. The operational standards and data structure of PCS–MCR are designed for seamless comparability with and integration into the national system.

PCS–MCR retains operational responsibility for case ascertainment, abstraction, coding, quality control, and residency determination within its defined catchment area. National coordination ensures harmonization of reporting across population-based cancer registries nationwide. Data contributed to national systems remain subject to PCS–MCR quality control prior to submission.

4.4 Stakeholders and Interested Parties

PCS-MCR recognizes the interested parties whose requirements influence registry operations and who are identified in Table 2.

Table 2. Interested Parties of Philippine Cancer Society - Manila Cancer Registry

Interested Party	Expectation/s
Residents of the defined catchment area	Accurate, confidential public health surveillance
Reporting hospitals and diagnostic facilities	Standardized reporting procedures and data protection
Department of Health	Compliant, high-quality cancer incidence data
Philippine Statistics Authority and Local Civil Registry Offices	Lawful data exchange and mortality verification
Academic and research institutions	Valid, reproducible, de-identified datasets
International cancer surveillance bodies (IARC/IACR)	Methodological compliance and data comparability

Data sharing agreements or memorandum of agreements are maintained between PCS-MCR and reporting hospitals or diagnostic facilities. Coordination and letters of request are maintained and regularly updated with local civil registry offices.

PCS–MCR monitors stakeholder requirements through legal review, regulatory updates, committee oversight, and performance evaluation mechanisms described in Sections 5 and 8. Review mechanisms for addressing the needs of these parties include the distribution of Annual

Registry Reports, which serve as the primary communication and accountability tool for the registry's performance, findings, and operational status.

4.5 Geographic Coverage and Catchment Area

The catchment area of the Philippine Cancer Society – Manila Cancer Registry consists of the following cities within the National Capital Region:

- Caloocan City
- Manila City
- Pasay City
- Quezon City

PCS–MCR is responsible for capturing all eligible incident cancer cases occurring among usual residents of these cities, regardless of where diagnosis or treatment is rendered.

Population denominators for incidence rate calculation shall be based on the most recent official population statistics released by the Philippine Statistics Authority. Registry analyses shall clearly specify the population reference year used.

The defined catchment area constitutes the population base for all incidence calculations conducted by PCS–MCR. Only cases meeting residency criteria defined in Section 6 shall be included in official incidence and mortality reporting.

4.6 Residency Criteria

For inclusion in the registry, a case must meet the residency criteria defined as follows:

- The individual's usual place of residence at the time of cancer diagnosis is within the defined catchment area.
- Diagnosis or treatment outside the catchment area does not exclude inclusion if residency criteria are met.
- Individuals residing outside the catchment area at the time of diagnosis are excluded from incidence calculations, even if diagnosed within facilities located inside the catchment area.

Residency determination shall follow structured verification procedures defined in Section 6, including hierarchical resolution of conflicting addresses, coded geographic assignment, and documentation of decision rules. Only cases confirmed as usual residents of the catchment area at the time of incidence shall be included in official analytical datasets. Subsequent relocation of the patient outside the PCS–MCR catchment area after diagnosis does not alter registry inclusion. Cases remain part of the registry if residency criteria were met at the time of diagnosis.

Conversely, individuals who become residents of the catchment area after diagnosis are not included in incidence statistics if the cancer was diagnosed while they were residents of another jurisdiction.

4.7 Organizational Risk and External Environment

PCS–MCR recognizes that cancer registration operates within a dynamic legal, technological, and public health environment. The registry therefore monitors internal and external issues that may affect its ability to achieve accurate, complete, and timely cancer surveillance within its defined catchment area.

4.7.1 External Factors

The following external issues may influence registry operations:

- Legislative and regulatory changes, including amendments to Republic Act No. 11215, Republic Act No. 10173, and related Department of Health issuances
- Modifications in national reporting structures under the National Cancer Registry and Monitoring System
- Changes in hospital ownership, hospital administration, mergers, closures, or electronic medical record systems that affect case ascertainment
- Variations in civil registration processes affecting mortality data availability
- Advances in diagnostic technologies, staging systems, and cancer classification standards (e.g., ICD-O updates, TNM revisions)
- Public health emergencies or disruptions that limit physical access to reporting facilities

PCS–MCR monitors such developments through regulatory review, coordination with reporting facilities, and participation in national and international cancer registry networks.

4.7.2 Internal Factors

Internal issues that may affect registry performance include:

- Staffing capacity and registrar competency
- Information technology infrastructure and database integrity
- Data security controls and confidentiality compliance
- Resource allocation for quality control and auditing activities
- Sustainability of funding and institutional support

PCS–MCR conducts periodic internal reviews to assess operational risks, including risks related to data completeness, accuracy, duplication, confidentiality breaches, and system downtime.

4.7.3 Risk Management Approach

PCS–MCR adopts a preventive risk-based approach consistent with ISO 9001 principles. Identified risks are evaluated in terms of:

- Likelihood of occurrence
- Potential impact on data quality, confidentiality, or legal compliance
- Mitigation measures and responsible personnel

Mitigation actions may include process revision, retraining of personnel, strengthening of data validation rules, enhancement of IT security controls, or formal coordination with reporting institutions.

Significant operational risks and corrective actions shall be documented and reviewed by registry leadership as part of ongoing quality management and performance evaluation activities described in Sections 5 and 8.

Operational risks identified under this section are formally documented, monitored, and reviewed through the PCS–MCR Risk Register maintained under Section 8 (Monitoring, Performance Indicators, and Continuous Improvement). The Risk Register records identified risks, risk ratings, mitigation measures, responsible personnel, and review status. Updates to the Risk Register are conducted during scheduled performance reviews or when significant operational changes occur.

5. LEADERSHIP AND ORGANIZATIONAL STRUCTURE

5.1 Institutional Governance

The Philippine Cancer Society – Manila Cancer Registry (PCS–MCR) operates under the institutional governance of the Philippine Cancer Society (PCS) Board of Trustees.

The Board of Trustees holds ultimate fiduciary and strategic authority over registry operations and ensures that PCS–MCR activities are aligned with the mission, vision, and long-term direction of the Philippine Cancer Society.

The President of the Philippine Cancer Society, as a member of the Board of Trustees, exercises executive oversight over registry operations. The President and the Cancer Registry Committee provide policy-level guidance, strategic direction, and institutional oversight but do not intervene in routine technical or operational decisions of the registry.

A Cancer Registry Committee, constituted by and composed of members of the Board of Trustees, provides dedicated technical and policy oversight for registry operations. The Committee derives its authority from the Board of Trustees and is responsible for:

- Reviewing and approving registry policies
- Providing strategic guidance for development and expansion
- Reviewing registry performance indicators
- Ensuring alignment with national legislation and international standards
- Advising on sustainability and resource mobilization

The Committee functions as an oversight body and does not perform operational registry functions.

The Registry Director shall submit a formal operational and performance report at least once every two months to the President and Board of Trustees. The Cancer Registry Committee shall review registry performance, quality indicators, compliance status, and strategic developments as part of its oversight function.

The Chair and Members of the Cancer Registry Committee shall present registry-related updates during the Philippine Cancer Society Annual General Assembly in accordance with institutional governance procedures.

The composition of the Board of Trustees and the Cancer Registry Committee shall be maintained in Annex A (Organizational Structure) and may be updated as necessary without requiring revision of this SOP.

5.2 Registry Director

The Registry Director serves as the chief operational and technical lead for PCS–MCR and is responsible for implementing all registry functions in accordance with this SOP, applicable national laws, and international cancer registration standards.

The Registry Director is accountable to the Board of Trustees and reports operationally through the President.

5.2.1 Provide overall leadership and management of registry operations.
5.2.2 Ensure compliance with Republic Act No. 11215, Republic Act No. 10173, relevant Department of Health issuances, and applicable institutional policies.
5.2.3 Implement technical policies and procedural standards approved by the Cancer Registry Committee.
5.2.4 Ensure the integrity, completeness, validity, comparability, and timeliness of registry data.
5.2.5 Approve operational procedures, quality control protocols, and validation processes.
5.2.6 Ensure adequate staffing, supervision, and competency development of registry personnel.
5.2.7 Oversee data analysis, reporting, publication, and official dissemination of registry outputs.

5.2.8 Ensure implementation of confidentiality safeguards and access control procedures.
5.2.9 Review registry quality indicators including MV%, DCO%, unknown primary percentage, and unknown age percentage.
5.2.10 Coordinate with the Department of Health, reporting facilities, regulatory authorities, and international cancer surveillance bodies.
5.2.11 Approve analytical dataset finalization dates and authorize batch closure.
5.2.12 Designate an alternate officer during temporary absence.

The Registry Director retains ultimate accountability for registry quality assurance, methodological integrity, and legal compliance.

5.3 Registry Manager

The Registry Manager is responsible for day-to-day technical supervision and coordination of registry operations and reports directly to the Registry Director.

The Registry Manager shall:

5.3.1 Supervise daily registry activities, including case finding, abstraction, coding, and data entry.
5.3.2 Coordinate active case finding across reporting facilities within the defined catchment area.
5.3.3 Review consolidated cases for completeness, internal consistency, and adherence to coding standards prior to database finalization.
5.3.4 Reject incomplete or inconsistent case abstractions and require corrective action by the responsible registrar, with documentation of such actions.
5.3.5 Exercise final authority over record linkage decisions, including complex merge determinations requiring multi-variable review
5.3.6 Convene consensus review with at least two additional registrars for ambiguous linkage cases; unresolved cases shall be escalated to the Registry Director
5.3.7 Monitor duplicate resolution, record linkage, and residency verification procedures.
5.3.8 Conduct periodic internal quality checks
5.3.10 Maintain documentation of quality control activities
5.3.11 Provide technical guidance, mentorship, and competency supervision for cancer registrars.

All corrective actions, rejected abstractions, and significant data quality issues shall be documented and reported to the Registry Director as part of the registry's quality monitoring framework.

5.4 Cancer Registrars

Cancer Registrars report directly to the Registry Manager and operate under the supervision of the Registry Director. Cancer Registrars are responsible for the accurate identification, abstraction, coding, and preliminary validation of eligible cancer cases within the defined catchment area.

Cancer Registrars shall:

5.4.1 Conduct active case finding in designated and authorized reporting facilities
5.4.2 Abstract complete and accurate demographic, clinical, diagnostic, staging, and treatment information from source documents in accordance with registry standards.
5.4.3 Apply residency and eligibility screening rules during abstraction
5.4.4 Perform preliminary internal consistency checks
5.4.5 Participate in record linkage and duplicate resolution processes
5.4.6 Correct errors as directed by the Registry Manager
5.4.7 Maintain strict confidentiality

Final coding of primary site, morphology, basis of diagnosis, extent of disease, and metastasis shall be performed after record linkage and consolidation in accordance with Section 6.

Registrars shall undergo supervised training prior to independent abstraction.

5.5 Statistician / Data Analyst

The Statistician or Data Analyst is responsible for the statistical analysis, interpretation, and reporting of registry data in accordance with established epidemiologic standards.

The Statistician shall:

5.5.1 Conduct statistical analysis of incidence, mortality, and survival data in accordance with internationally recognized methodologies.
5.5.2 Calculate crude rates, age-specific rates, and age-standardized rates using approved standard populations.
5.5.3 Support the generation of registry quality indicators, including MV%, DCO%, timeliness, and completeness assessments.
5.5.4 Collaborate with the Registry Director and Registry Manager to validate analytical outputs prior to publication or dissemination.
5.5.5 Contribute to technical reports, publications, and official statistical releases of PCS–MCR.
5.5.6 Perform analysis exclusively on de-identified datasets prepared in accordance with approved data governance and confidentiality procedures.
5.5.7 Not have access to identifiable patient information unless explicitly authorized for approved methodological validation activities.
5.5.8 Maintain documentation of analytical methodologies to ensure reproducibility and transparency.

The Statistician shall not independently release registry data, statistical outputs, or publications. All official statistical reports and publications shall undergo technical review by the Registry

Director and institutional approval in accordance with the governance structure defined in Section 5.1.

5.6 Data Protection Oversight

The Philippine Cancer Society shall designate a Data Privacy Officer (DPO) in accordance with Republic Act No. 10173. The DPO provides institutional oversight for data protection compliance.

PCS–MCR shall designate an internal Data Protection Focal Person responsible for:

- Ensuring implementation of registry-level data security measures
- Monitoring access controls
- Coordinating with the DPO on compliance matters
- Assisting in risk assessment and breach response procedures
- Providing oversight of confidentiality and security safeguards

All registry staff must maintain strict confidentiality of identifiable patient information. Access to identifiable data is restricted to authorized registry personnel only. Registry databases are password protected and maintained within secure institutional systems.

All registry personnel must execute a Confidentiality Agreement prior to being granted access to identifiable registry data. The Data Protection Focal Person is authorized to recommend suspension of access privileges in cases of suspected non-compliance. Any suspected data breach shall be immediately reported to the Registry Director and the PCS Data Privacy Officer in accordance with institutional incident response procedures. Final decisions on suspension or revocation of access privileges shall be made by the Registry Director in coordination with the PCS Data Privacy Officer.

The Data Protection Focal Person shall not exercise operational control over registry methodology or analytical outputs. The role is limited to oversight of confidentiality, security controls, and compliance with data protection regulations.

5.7 Lines of Authority and Reporting Structure

The organizational structure, formal lines of authority, and reporting hierarchy for all personnel involved in cancer registration are graphically represented in Figure 2. Authority within PCS–MCR is structured to ensure separation between governance oversight, operational management, technical review, and statistical analysis. No single role shall exercise unilateral control over data collection, coding, analysis, and release.

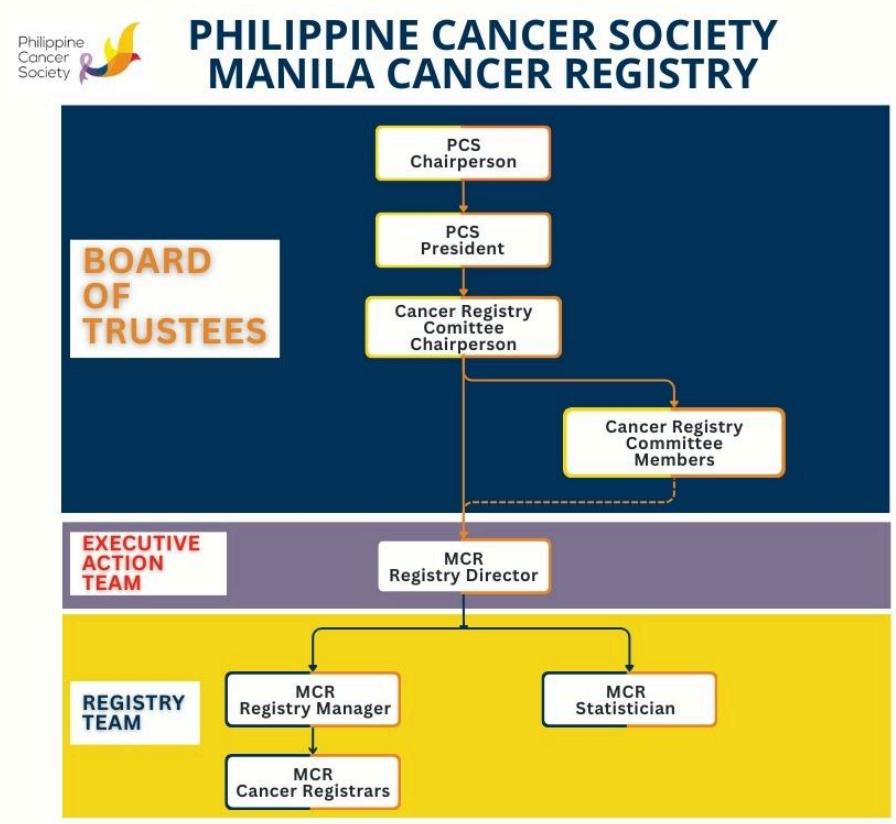
Registry personnel shall disclose any potential conflicts of interest that may affect objectivity in data reporting or analysis.

Technical coding and linkage decisions shall be made by the Registry Manager within delegated authority. Final methodological interpretation rests with the Registry Director. Policy-level decisions, procedural modifications, and major operational changes shall require approval in accordance with the governance structure defined in Section 5.1.

In cases of unresolved technical disagreement, matters shall be escalated to the Registry Director for final determination. Where policy implications arise, the issue shall be referred to the President and Cancer Registry Committee.

Quality review shall, where feasible, be performed by personnel other than the original abstractor.

Figure 2. Philippine Cancer Society - Manila Cancer Registry Organizational Chart



5.8 Competency and Training Requirements

All PCS–MCR personnel must demonstrate competence appropriate to their roles, documented through formal education, professional experience, and successful completion of role-specific training. A core requirement for all Cancer Registrars (5.4) and the Registry Manager (5.3) is Formal Cancer Registration Certification from recognized bodies such as the WHO, the Department of Health (DOH), or any of the trainings provided by the existing Philippine population-based cancer registries.

Competency and training requirements shall include the following key concepts:

- Cancer registration methodology
- Coding systems such as ICD-O
- Essential TNM training
- IARC CanReg training
- Understanding of residency rules and multiple primary determination
- Familiarity with data validation procedures
- Knowledge of confidentiality and data protection principles

Prior to independent case ascertainment or abstraction, newly appointed Cancer Registrars shall conduct tasks under supervision. Competency shall be demonstrated through satisfactory completion of supervised case abstraction and coding as evaluated by the Registry Manager.

Participation in continuing education aligned with IARC and international standards shall be encouraged. Training records shall be maintained. Where competency gaps are identified, corrective supervision or retraining shall be implemented.

6. CANCER REGISTRATION OPERATIONAL PROCESS

6.1 Process Control Framework

The Philippine Cancer Society – Manila Cancer Registry (PCS–MCR) implements a controlled, documented, and auditable cancer registration system consistent with:

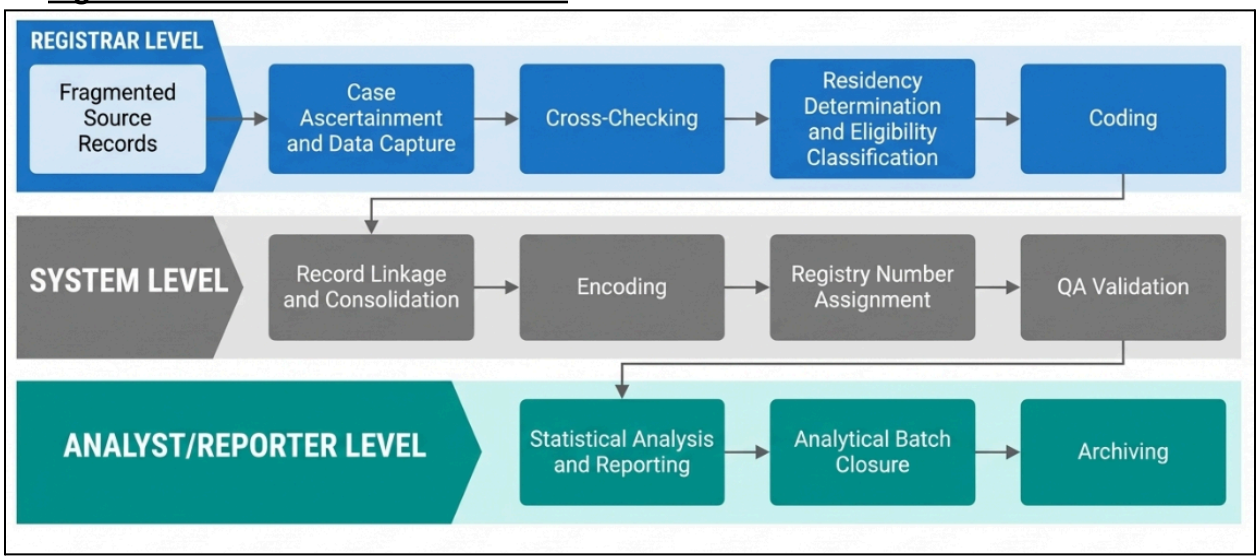
- IARC Scientific Publication No. 95)
- IARC Technical Publication No. 43 (Planning and Developing PBCRs)
- WHO Handbook for Standardized Cancer Registries (1976)
- IARC Manual for Cancer Registry Personnel (1995)
- AFCRN Standard Procedure Manual (Version 5, 2024)
- Essential TNM User's Guide (Version 4.2, 2024)
- IARC Multiple Primary Rules
- ICD-O (current edition adopted by registry)
- SEER Self-Instructional Manual for Cancer Registries

The registry operational process is designed to ensure completeness of case ascertainment, validity of data elements, comparability across time and regions, reproducibility of statistical outputs, traceability of all decision rules All activities occur within defined diagnosis-year collection cycles and under documented authority levels defined in Section 5.

The process consists of the following mandatory sequential phases:

1. Retrospective Case Ascertainment
2. Data Capture and Source Documentation
3. Record Linkage and Consolidation
4. Cross-Checking
5. Residency Determination
6. Eligibility Classification
7. Incidence Date and Date of Last Contact Determination
8. Coding and Classification
9. Encoding
10. Registry Number Assignment
11. Quality Control and Validation
12. Statistical Analysis and Reporting
13. Analytical Dataset Finalization and Batch Closure
14. Record Retention and Archiving

Figure 3. Process Control Framework



6.2 Overview of the Cancer Registration Cycle

PCS–MCR conducts retrospective population-based cancer registration.

Each operational cycle covers a defined diagnosis period (e.g., 2018–2022). Case ascertainment for a cycle may occur several years after diagnosis to ensure completeness of data capture, including treatment and mortality information. The stages of the cancer registration cycle are identified in Table 3.

The PCS–MCR registration workflow follows the internationally recognized methodology for population-based cancer registries described in IARC Scientific Publication No. 95 and IARC Technical Publication No. 43.

A key principle of this methodology is that consolidation of records referring to the same individual must occur prior to coding, incidence date determination, and statistical analysis. PCS–MCR therefore implements a sequential process in which records collected from multiple facilities are first linked and consolidated into a single patient abstract.

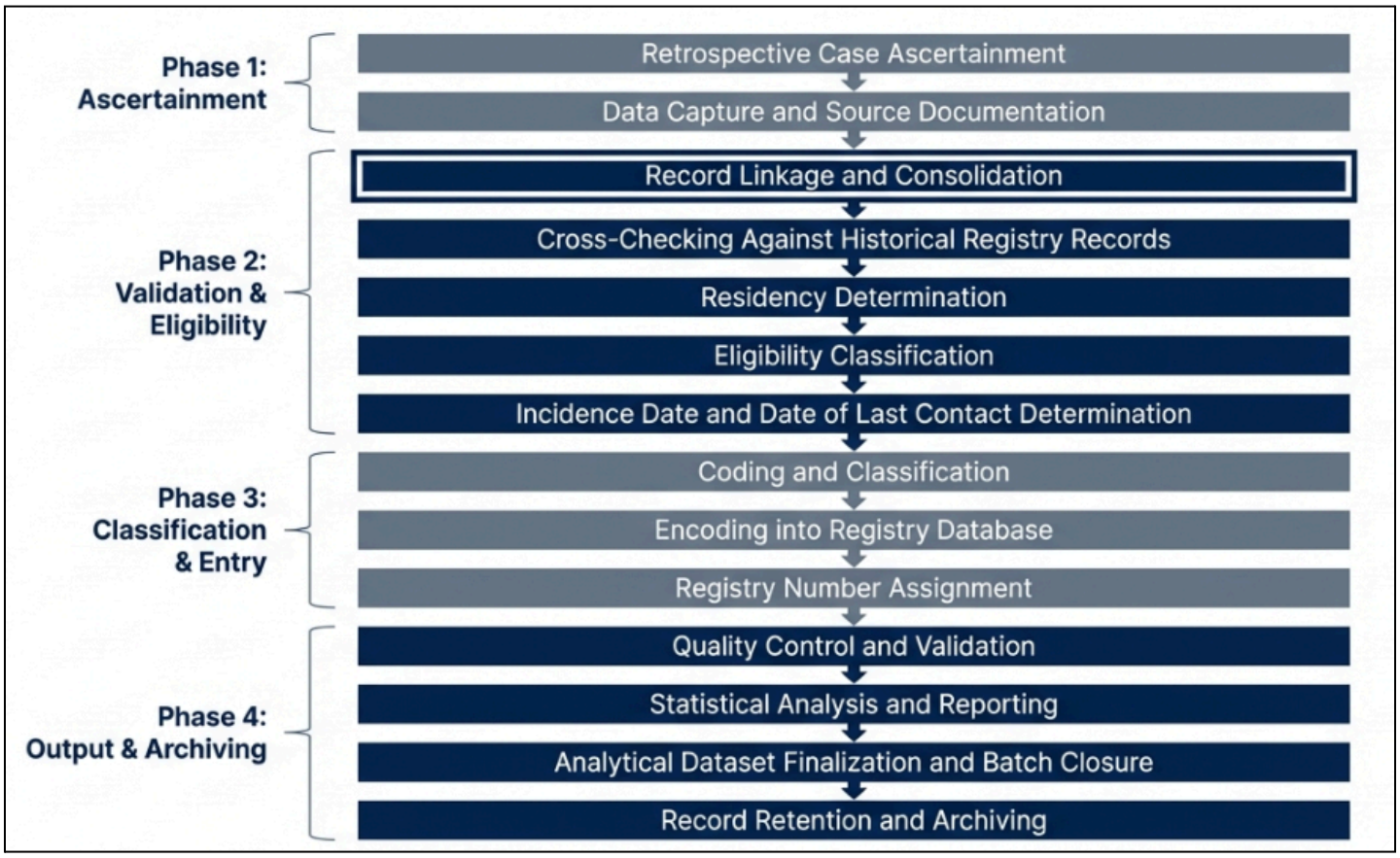
This structured sequence ensures that coding, incidence date determination, and statistical analysis are performed only on consolidated eligible resident cases, thereby maintaining accuracy of incidence statistics and preventing duplicate counting.

Table 3. Philippine Cancer Society - Manila Cancer Registry Cancer Registration Cycle

Stage	Responsible Authority	Output
Case ascertainment	Cancer Registrars	Source records captured
Record linkage	Senior Cancer Registrars Registry Manager	Consolidated patient abstract / record
Coding	Cancer Registrars	Final coded abstract
Validation	Senior Cancer Registrars Registry Manager	Clean dataset
Analysis	Statistician	Statistical outputs
Approval	Registry Director	Approved report
Finalization	Registry Director	Locked analytical dataset

The methodological sequence is constant regardless of software platform.

Figure 4. Cancer Registry Data Lifecycle Diagram



6.3 Active Case Finding / Case Ascertainment

6.3.1 Definition

Active case finding, also referred to as case ascertainment, is the structured, retrospective identification and documentation of all potential cancer cases from multiple independent data sources.

This approach is consistent with IARC Scientific Publication No. 95 and AFCRN Version 5 standards requiring multi-source ascertainment to ensure completeness.

6.3.2 Scope of Data Sources

Cancer Registrars are deployed to review records from:

- Medical records departments
- Cancer institutes or oncology centers
- Outpatient clinics
- Chemotherapy units
- Radiation therapy units
- Histopathology laboratories
- Radiology departments
- Nuclear medicine units, including PET scan services
- Local Civil Registry Offices (death registry records)

In addition to the listed sources, PCS–MCR may include other departments, service units, or facilities where cancer diagnosis, treatment, supportive care, or end-of-life care records are generated (e.g., hospice units, palliative care services, ambulatory infusion units, new specialty diagnostic units), when deemed necessary to maintain completeness of case ascertainment. The inclusion of new sources shall be documented by the Registry Manager and approved by the Registry Director as part of the annual review of data sources.

6.3.3 Case Ascertainment / Active Case Finding Procedure

Step 0: Facility Coordination and Notification

Prior to resumption of case ascertainment activities in any reporting facility, PCS–MCR issues formal written notification to the facility's designated focal person or authorized office. The notification identifies the diagnosis years covered by the collection cycle, the names of authorized registrars assigned to the facility, the departments or units to be accessed, and the categories of variables to be collected. Where facilities are able to provide pre-identified lists of potential cancer records (e.g., oncology census lists, pathology line lists, tumor registries), these may be used as guides to facilitate retrieval, provided that registrars independently validate each record prior to data capture.

Step 1: Identify Target Diagnosis Years

Registrar confirms applicable diagnosis-year range for the current collection cycle.

Step 2: Access Authorized Records

Registrar reviews admission logs, pathology logs, oncology clinic lists, death registers, imaging logs.

Step 3: Identify potential cancer indicators

Registrar flags records with confirmed malignant diagnosis, clinical diagnosis of cancer, suspicious or presumed malignancy, metastatic carcinoma, death certificate mentioning malignancy, HSIL / CIN III, and other designated reportables.

Step 4: Record Each Encounter as Separate Entry

Each document or encounter is recorded as one row in the collection file to preserve traceability.

Step 5: Capture Verbatim Source Information

Diagnosis and clinical details are recorded exactly as written.

DECISION RULE 6-A: HANDLING OF SUSPICIOUS for MALIGNANCY CASES

If documentation states:
- "Suspicious for malignancy"
- "Probable carcinoma"
- "Compatible with malignancy"

→ The case shall be collected and abstracted.
→ Coding shall remain pending until confirmation.
→ Case shall not be included in incidence analysis unless behavior /3 is confirmed.

If documentation states:
- "Rule out malignancy"
- "Possible malignancy"
- "Questionable"

→ Case shall be recorded but flagged as pending review.
→ No coding shall occur until confirmation.

(Aligned with AFCRN reporting guidance and IARC principles.)

This approach ensures completeness without inflating incidence.

6.3.4 Case Ascertainment Completeness Evaluation

To ensure that cancer case ascertainment within the registry catchment population is as complete as possible, the PCS–MCR performs periodic evaluations of case ascertainment completeness.

Completeness evaluation is conducted after each data collection cycle and prior to finalization of analytical datasets.

The evaluation is conducted by the Registry Manager and reviewed by the Registry Director.

- The indicators used to evaluate completeness and data validity include:
- Morphologically Verified Percentage (MV%)
- Death Certificate Only Percentage (DCO%)
- Proportion of cases with unknown primary site
- Proportion of cases with unknown age
- Mortality-to-incidence ratio (when mortality data are available)
- Contribution of individual reporting sources

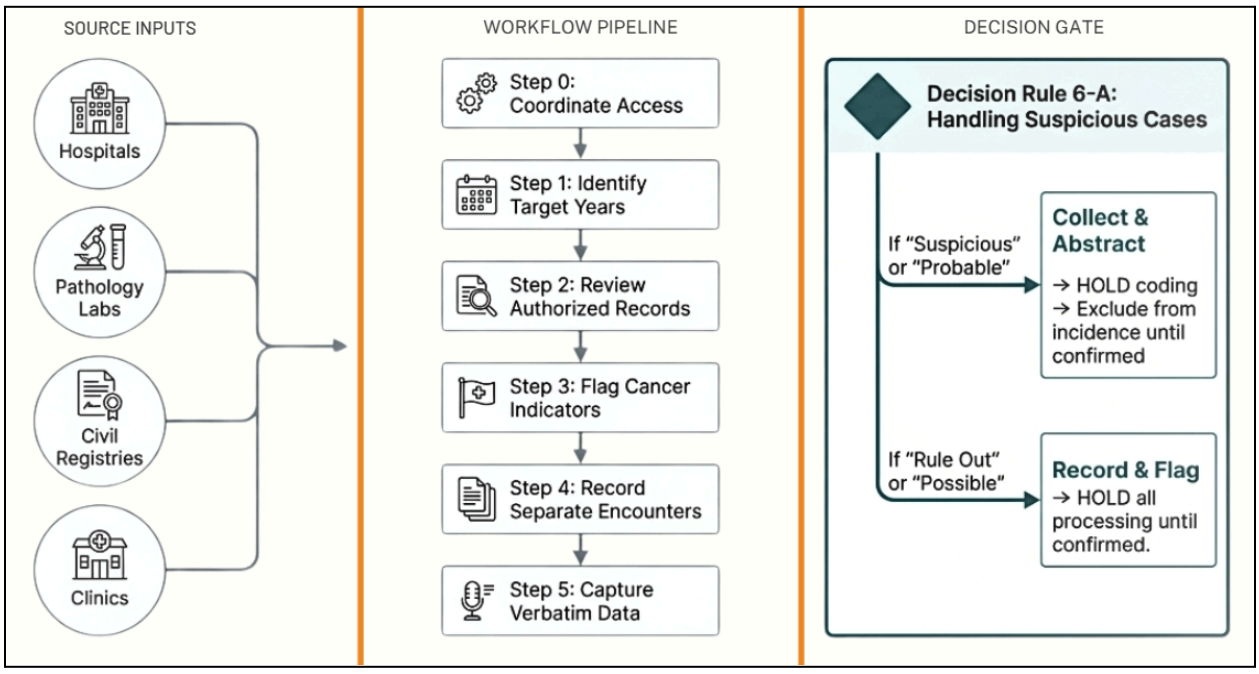
The definitions and target benchmarks for these indicators are specified in Section 8.2.

If indicator values fall outside the target ranges defined in Section 8.2, the registry shall conduct a completeness review which may include:

- targeted case finding in under-represented reporting facilities
- re-review of pathology laboratory records
- enhanced death certificate trace-back procedures
- verification of case linkage procedures

Results of completeness evaluations are documented as part of the Annual Registry Quality Review.

Figure 5: Retrospective Case Ascertainment



6.4 Data Variables Collected During Case Ascertainment

PCS–MCR collects core and extended variables consistent with the IARC Manual for Cancer Registry Personnel. Data collection is structured into the following domains:

6.4.1 Administrative and Collection Variables

6.4.1.1 Date collected
6.4.1.2 Reporting registrar
6.4.1.3 Name of Facility / Hospital / Local Civil Registry
6.4.1.4 Source of data

6.4.2 Patient Identification Variables

6.4.2.1 Hospital case number
6.4.2.2 Last name
6.4.2.3 First name
6.4.2.4 Middle name
6.4.2.5 Date of birth
6.4.2.6 Sex
6.4.2.7 Civil status
6.4.2.8 Nationality
6.4.2.9 Address of usual residence (specifiying Municipality or City and Barangay if Manila City)
6.4.2.11 Place of birth
6.4.2.12.Contact Number
6.4.2.13 Usual Occupation

All identifiers are collected exactly as documented in to maximize linkage accuracy.

6.4.3. Clinical and Diagnostic Variables

Collected exactly as documented in source records.

6.4.3.1 Full cancer diagnosis
6.4.3.2 Histopathology number
6.4.3.3 Date specimen received
6.4.3.4 Histopathology result
6.4.3.5 TNM (if recorded)
6.4.3.6 Stage or grade (if recorded)
6.4.3.7 CT scan results
6.4.3.8 PET scan results
6.4.3.9 Date imaging was done
6.4.3.10 Date of admission
6.4.3.11 Date of discharge
6.4.3.12 Date of outpatient consultation

Staging may later be derived using Essential TNM if not explicitly recorded.

6.4.4 Treatment Variables

6.4.4.1 Surgery (type)
6.4.4.2 Date of surgery
6.4.4.3 Radiotherapy (first and last date)
6.4.4.4 Chemotherapy (first and last date)
6.4.4.5 Immunotherapy (first and last date)
6.4.4.6 Hormone therapy (first and last date)
6.4.4.7 Earliest treatment date

6.4.5 Mortality Variables

Collected from hospital and local civil registry records:

6.4.5.1 Date of death
6.4.5.2 Usual residence recorded on Death Certificate
6.4.5.3 Place of death (if house or hospital)
6.4.5.4 Name of hospital recorded on Death Certifiate
6.4.5.5 Immediate, antecedent, underlying causes of death, and other significant conditions contributing death
6.4.5.6 Medical attendance at the time of death
6.4.5.7 Certifying authority (if private physician, public health officer, or hospital authorities)
6.4.5.8 Name of physician certifying the death
6.4.5.9 Hospital or clinic of doctor certifying the death
6.4.5.10 Autopsy status (if done, not done, or unknown)
6.4.5.11 Diagnosis on Autopsy

Death certificate data are integrated during record linkage.

Table 4. Control Table: Variable Finalization Timing

Variable Type	Collected During Ascertainment	Finalized After Linkage
Verbatim diagnosis	Yes	Yes
Primary site	No	Yes
Morphology	No	Yes
Basis of diagnosis	No	Yes
Extent of disease	No	Yes
Metastasis site	No	Yes
Initial Treatment	No (derived)	Yes
Incidence Date	No (derived)	Yes
Date of Last Contact	No (derived)	Yes
Patient Status	No (derived)	Yes
This sequencing ensures coding is based on consolidated data from all facilities. Incidence date and date of last contact are derived variables assigned only after record linkage, consolidation, and historical record verification have been completed.		

6.5 Death Certificate Only Case Investigation (DCO Procedure)

A Death Certificate Only (DCO) case is a cancer case identified through a death certificate where no prior record of the cancer diagnosis is found in registry sources at the time of initial linkage. DCO cases are important indicators of case ascertainment completeness and require additional investigation.

6.5.1 Identification of Potential DCO Cases

During record linkage and mortality integration, cases are flagged as potential DCO when:

- the death certificate lists cancer as the underlying or contributing cause of death
- no prior medical record for the cancer diagnosis exists in the registry database

These cases are temporarily classified as potential DCO.

6.5.2 Trace-Back Investigation

For each potential DCO case, the registry shall attempt to identify the diagnostic source through the following trace-back procedure:

1. Review hospital records of the reporting facility listed on the death certificate
2. Review pathology laboratory records
3. Review oncology clinic records
4. Review treatment facility records
5. Review imaging department records if applicable

If a diagnostic record is identified, the case is converted from potential DCO to standard incident case, and the appropriate incidence date is assigned.

6.5.3 Classification Outcomes

After investigation, cases are classifed as follows:

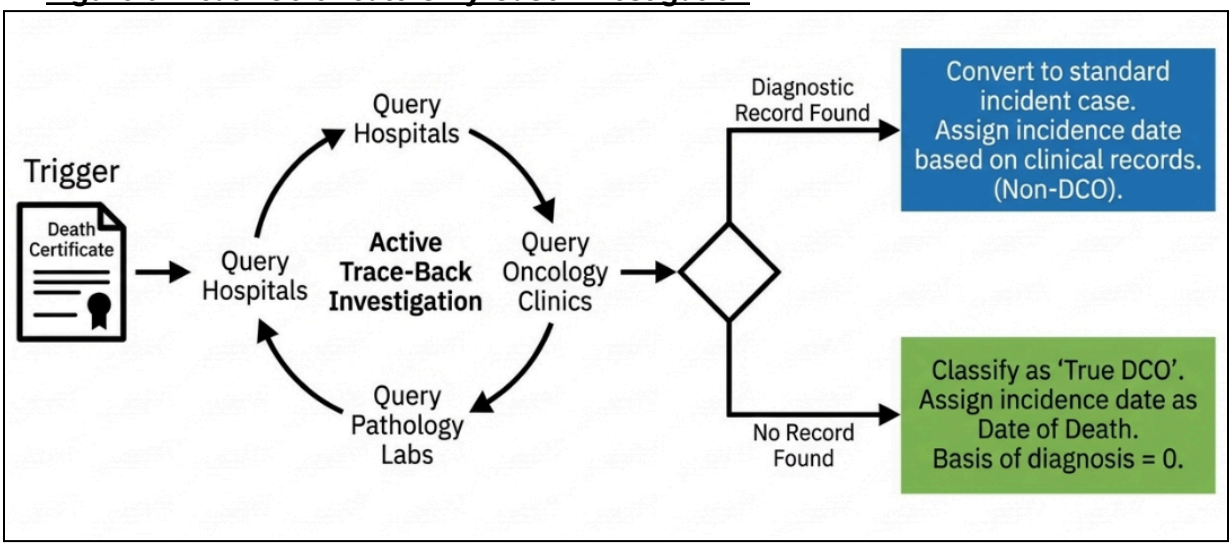
1. Non-DCO: Diagnostic record found during trace-back investigation
2. True DCO: No diagnostic record identified after investigation

True DCO cases remain in the registry but are coded accordingly.

For true DCO cases, incidence date is assigned as date of death and basis of diagnosis is coded as death certificate.

The proportion of DCO cases is monitored annually as a completeness indicator. High DCO proportions may indicate incomplete case finding and trigger additional case ascertainment review.

Figure 6. Death Certificate Only Case Investigation



6.6 Record Linkage and Consolidation

6.6.1 Purpose and Standards Alignment

Record linkage and consolidation are conducted to ensure that all records referring to the same individual are identified, merged, and represented as a single consolidated patient record prior to coding, incidence date determination, and analysis. This process is consistent with:

- IARC Scientific Publication No. 95 (Cancer Registration: Principles and Methods)
- IARC Technical Publication No. 43 (Planning and Developing PBCRs)
- AFCRN Standard Procedure Manual (Version 5, 2024)
- WHO Handbook for Standardized Cancer Registries (1976)

6.6.2 Procedural Steps

Step 1: Compile All Collected Source Entries

All entries captured during active case ascertainment are aggregated into the collection file for the current diagnosis-year cycle. Each entry represents one source encounter and contains verbatim identifiers and source-specific information.

Step 2: Automated Preliminary Matching

Where digital tools are available, preliminary matching is performed using exact matching on:

- Last name
- First name
- Middle name
- Date of birth

Exact matches are automatically grouped as potential duplicates.

Step 3: Manual Review of Near Matches

Records not matched automatically but showing potential similarity are reviewed manually by Cancer Registrars using:

- Minor spelling variations
- Phonetic similarity
- Sex
- Address
- Diagnosis
- Dates of admission or consultation
- Hospital number (within same facility)

Step 4: Escalation to Registry Manager

If uncertainty exists regarding whether two or more records refer to the same individual, the case is escalated to the Registry Manager for determination.

6.6.3 Senior Registrar Review

All consolidated records undergo review in a controlled file, digital page, or system accessible only to Senior Cancer Registrars.

Within this controlled environment, Senior Cancer Registrars are authorized to:

- Correct Unique Patient Identifiers (UPIs) after verifying supporting variables
- Confirm that two records represent the same person and merge them
- Confirm that records represent different individuals
- Request additional source verification before final decision

Only after confirmation by a Senior Cancer Registrar is the consolidated record marked for upload to the main registry database viewable by all authorized users. This controlled staging step serves as a formal quality gate prior to registry-level finalization.

DECISION RULE 6-B: MERGE AUTHORITY

If identifiers are identical and supporting variables are consistent → merge.

If identifiers differ but supporting variables strongly suggest same individual
→ Senior Cancer Registrar may correct UPI and merge, with documentation.

If identifiers appear similar but supporting variables conflict
→ do not merge until additional verification.

All merge decisions must be confirmed by a Senior Cancer Registrar prior to upload to the main registry database.

6.6.4 Record Consolidation

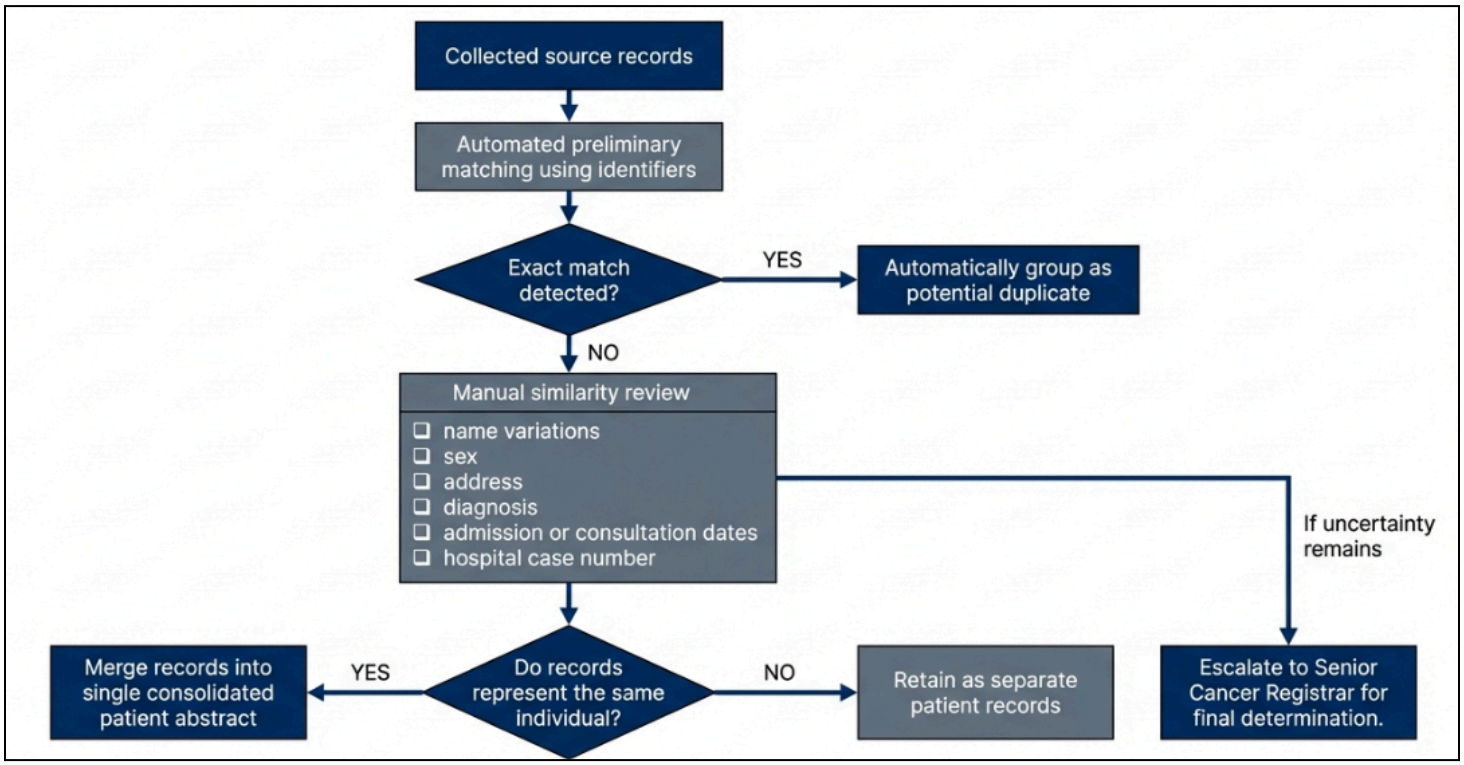
After linkage decisions are finalized, all records referring to the same individual are consolidated into a single patient-level abstract.

Consolidation integrates:

- Hospital records
- Pathology results
- Imaging reports
- Oncology clinic visits
- Treatment records
- Death certificate data

Coding and incidence date determination shall not occur prior to completion of linkage and consolidation.

Figure 7. Record Linkage Decision Algorithm



6.7 Cross-Checking Against Historical Registry Records

After consolidation of current-cycle data, the record is cross-checked against existing PCS–MCR registry database.

Step 1: Historical Database Query

The consolidated patient record is entered into the reference registry database (e.g., CanReg) using verified UPIs.

Step 2: Determine Status

If the system identifies an existing registry number:

- The case is classified as an existing patient record.
- Newly collected information is used to update the historical record.

If no match is identified:

- The case is classified as a new registry patient.

Step 3: Establish Earliest Incidence Date Across All Records

If the case is an existing patient record, the incidence date is the earliest date recorded across both historical and current consolidated data.

If the case is a new registry patient, incidence date is determined from the current consolidated data according to Section 6.9.

DECISION RULE 6-C: HISTORICAL MATCH

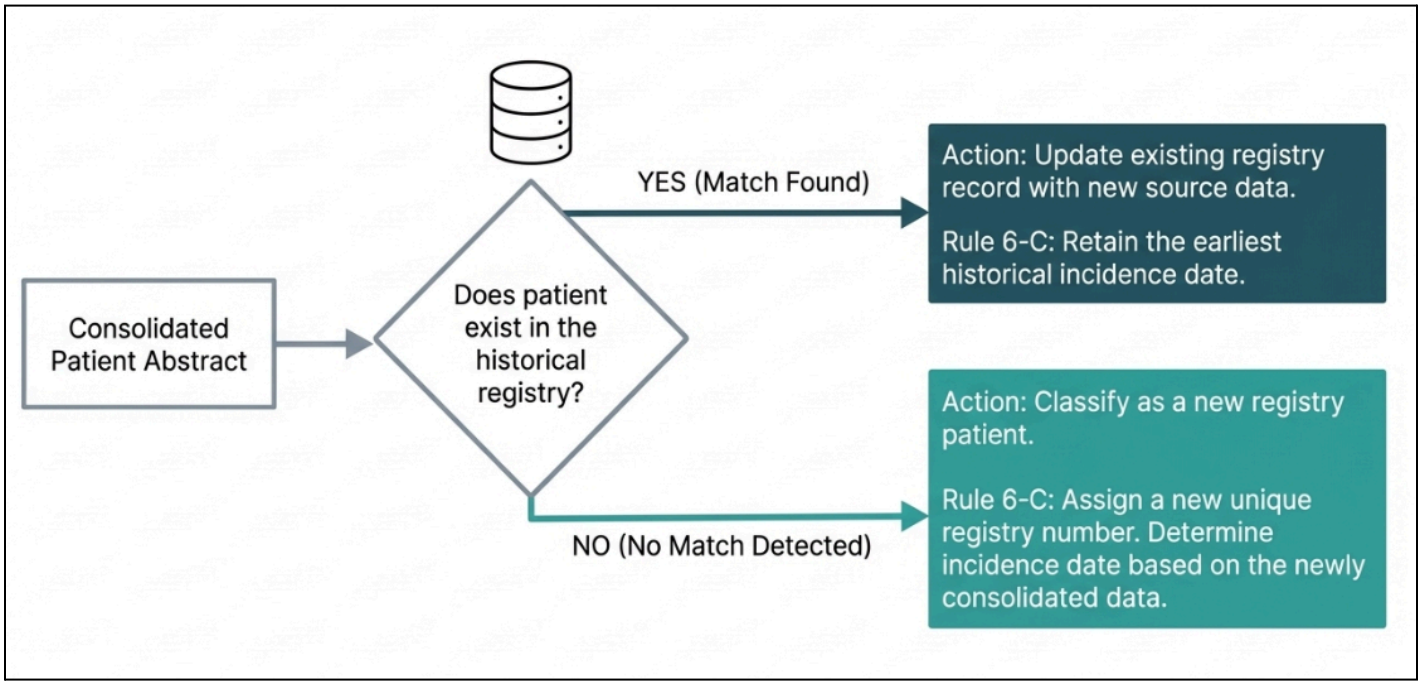
Existing registry number detected → update existing record; retain earliest historical incidence date.

No registry match detected → assign new registry number; determine incidence date from consolidated data.

Inclusion in statistical reporting is based solely on final incidence year after cross-check.

This step directly determines inclusion in cycle-specific reports (e.g., 2018–2022).

Figure 8. Cross-Checking



6.8 Residency Determination

Residency determination occurs after record linkage and cross-checking against historical registry records. Residency is defined as the patient's usual place of residence at the time of cancer diagnosis.

For the purposes of the PCS–MCR registry, a case is considered eligible for inclusion if the patient was a usual resident of the registry catchment area at the time the cancer was first diagnosed, regardless of the location of diagnosis or treatment.

Subsequent relocation of the patient outside the catchment area after diagnosis does not affect registry inclusion if residency criteria were satisfied at the time of diagnosis.

6.8.1 Procedural Steps

Residency determination follows a structured verification process to ensure that registry inclusion is based on the patient's usual place of residence at the time of diagnosis.

Step 1: Extract All Documented Addresses

All recorded addresses from available records are reviewed, including:

- medical records
- outpatient consultation records
- admission records
- pathology request forms
- diagnostic reports
- death certificates, when available

The registrar records all documented addresses in the collection file prior to determining residency status.

Step 2: Apply Address Hierarchy

If multiple or conflicting addresses are identified, the following hierarchy is applied to determine the most appropriate address for residency determination:

1. Address documented closest to the date of diagnosis
2. Most frequently documented address across records
3. Most recently documented address near diagnosis date
4. Address recorded in death certificate (if diagnosis date cannot be determined from earlier records)

Registrars must prioritize addresses documented near the earliest clinical evidence of malignancy.

Step 3: Apply Geographic Coding

The validated address is mapped to registry-approved geographic codes.

Coding conventions used by PCS–MCR include:

- Barangay-level coding for Manila City
- City-level coding for Caloocan City, Pasay City, and Quezon City

Geographic coding is used to determine whether the address falls within the defined registry catchment area.

DECISION RULE 6-D: RESIDENCY DETERMINATION

If usual residence at time of diagnosis is within catchment area → classify as resident.

If outside catchment area → classify as non-resident.

Only resident cases are included in PCS-MCR incidence calculations.

Non-resident cases are retained for completeness and inter-registry coordination.

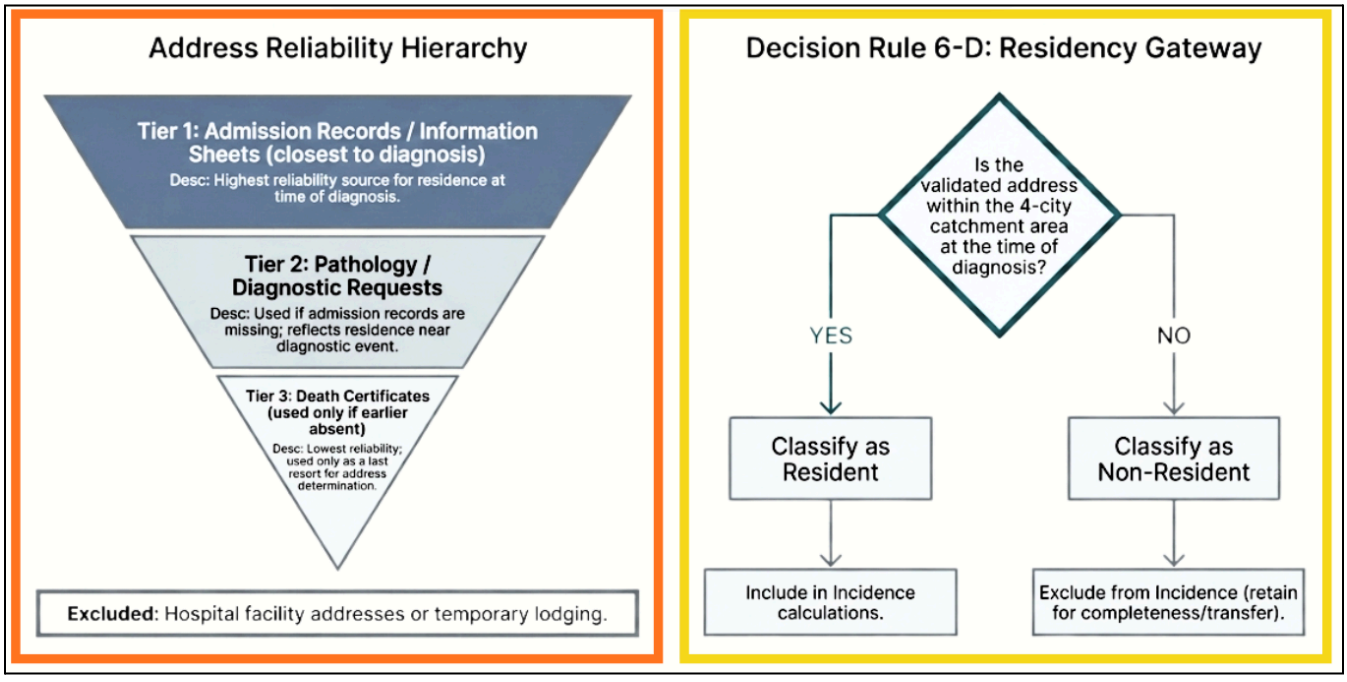
Step 4: Determine Catchment Area Eligibility

The validated address is compared with the official PCS-MCR catchment area:

- Quezon City
- Caloocan City
- Manila City
- Pasay City

If the patient's usual residence at the time of diagnosis falls within these jurisdictions, the case proceeds to eligibility classification and registry procesing. If the address falls outside these jurisdictions, the case is classified as a non-resident case.

Figure 9. Residency Determination



6.8.2 Handling Previously Registered Cases

If cross-checking against the historical registry identifies an existing registry record for the same patient, the registrar shall verify the residency status recorded at the time of the original diagnosis.

Cases previously registered while the patient was a resident of the PCS–MCR catchment area shall remain part of the registry dataset even if the patient has subsequently relocated outside the catchment area.

6.8.3 Handling Non-Resident Cases

Cases determined to be non-residents are not included in PCS–MCR incidence statistics. However, source records may be temporarily retained in the collection file for:

- documentation of case ascertainment activities
- completeness monitoring
- possible transfer to the appropriate population-based cancer registry when applicable

Non-resident cases shall not be encoded into the PCS–MCR incidence database unless they correspond to an already existing registry case.

6.8.4 Residency Ambiguity Resolution

In some cases, residency status cannot be determined directly because of incomplete, conflicting, or ambiguous address information. When this occurs, registrars shall apply the following resolution guidelines to determine the most probable usual place of residence at the time of diagnosis.

6.8.4.1 Temporary hospital or treatment address

If the address recorded refers to the hospital, treatment facility, or temporary lodging near the hospital, the registrar shall disregard the hospital address and identify the patient's permanent home address from admission records, referral forms, or identification documents.

6.8.4.2 Multiple residential addresses

If a patient has multiple residences recorded (for example, a provincial home and a Metro Manila address), the registrar shall use the address most closely associated with the patient's daily residence at the time of diagnosis, prioritizing addresses recorded in admission or consultation records.

6.8.4.3 Overseas workers or temporary migrants

If a patient is working abroad but maintains a permanent residence within the PCS–MCR catchment area and returns to that residence for treatment or consultation, the Philippine address may be considered the usual residence provided it is documented in medical records.

6.8.4.4 Incomplete address information

If only partial address information is available (for example, city name without barangay), the registrar shall use available contextual information from the record to determine the most probable jurisdiction. When the jurisdiction cannot be determined with reasonable certainty, the case shall be reviewed by the Senior Cancer Registrar.

6.8.4.5 Conflicting addresses across records

When records contain conflicting addresses across different facilities, the registrar shall prioritize:

1. Address documented closest to the date of diagnosis
2. Address recorded in admission documentation
3. Address appearing most consistently across records

6.8.4.6 Persons without Housing or Unknown Residence

If a patient does not have a fixed residential address at the time of diagnosis, the registrar shall attempt to determine the most probable usual place of residence using available documentation such as:

- admission records
- social worker notes
- identification documents
- civil registry records
- referral forms

If documentation indicates that the patient was habitually staying within the PCS–MCR catchment area at the time of diagnosis, the case may be classified as a resident case.

If no reliable information exists to determine the usual place of residence, the case shall be escalated to the Senior Cancer Registrar for review.

Cases with completely unknown residence shall not be included in PCS–MCR incidence statistics but may be documented in registry records for case ascertainment completeness monitoring.

6.8.4.7 Diagnosis Occurring Outside the Philippines

If the initial cancer diagnosis occurred outside the Philippines but the patient was a usual resident of the PCS–MCR catchment area at the time of diagnosis, the case may be included in the registry provided that sufficient medical documentation confirming the diagnosis is available.

Acceptable documentation may include:

- pathology reports
- diagnostic imaging reports
- physician certification of diagnosis
- treatment records from recognized medical institutions

If reliable documentation of the diagnosis cannot be obtained, the case shall not be registered as an incident case.

Cases diagnosed abroad but lacking sufficient documentation may be recorded in the collection file for reference but shall not be encoded into the registry incidence database.

6.8.4.8 Unresolvable cases

If residency cannot be determined after applying the above rules, the case shall be escalated to the Senior Cancer Registrar for final determination.

The decision of the Senior Cancer Registrar shall be documented in the collection file to ensure transparency and consistency in future audits.

6.8.5 Residency Verification Documentation Hierarchy

When multiple or conflicting addresses are present in source records, registrars shall evaluate the available documentation using the following hierarchy of evidentiary reliability. Sources listed higher in the table take precedence over those listed lower when determining usual residence at the time of diagnosis.

Table 5. Residency Verification Documentation Hierarchy

Documentation Source	Typical Location in Records	Reliability for Residency Determination	Operational Guidance
Admission record or patient information sheet	Hospital admission documents	Very High	Primary reference for residency determination because it is typically verified during patient registration
Outpatient consultation record	Physician consultation notes	High	Acceptable when admission records are not available; prioritize consultations closest to diagnosis
Pathology request form	Laboratory request documentation	High	Often completed by the treating physician and may contain the patient's declared address
Diagnostic imaging request form	Radiology request documentation	Moderate	May contain address information but sometimes reflects referring facility location
Hospital administrative record	Billing or registration database	Moderate	Useful when clinical records are incomplete but may contain abbreviated address information
Death certificate	Civil registry record	Moderate	Used when earlier medical records are unavailable; should not override admission records near diagnosis
Referral forms from another hospital	Inter-facility referral documentation	Moderate	May contain outdated addresses depending on referral timing
Verbal report documented in medical notes	Physician or nurse notes	Low	Used only when no formal documentation is available
Hospital address or temporary lodging address	Facility address used for administrative purposes	Not acceptable	Should not be used to determine residency

Additional Operational Guidance:
When evaluating conflicting addresses, registrars shall prioritize documentation recorded closest to the date of diagnosis and supported by official medical records.

If the available documentation does not allow reliable determination of the patient's usual residence, the case shall be reviewed by the Senior Cancer Registrar for final determination.

6.9 Case Eligibility and Reportable Neoplasms

PCS–MCR follows ICD-O behavior coding and IARC/AFCRN reporting standards.

Included in analysis and reporting:

- All malignant neoplasms coded behavior /3
- Hematologic malignancies
- Designated in situ lesions including CIN III / HSIL, VAIN III, VIN III
- All reportable entities listed in the registry's adopted reportable list

Suspicious or unconfirmed cases are retained in pending status and excluded from incidence analysis unless behavior /3 or designated reportable criteria are confirmed.

DECISION RULE 6-E: REPORTABILITY

Behavior /3 → include in analysis and reporting.

CIN III / HSIL and designated reportables → include in analysis.

Suspicious/pending → retain; exclude from incidence until confirmed.

6.10 Incidence Date and Date of Last Contact Determination

Incidence date is assigned only after:

- Linkage and consolidation
- Historical registry cross-check
- Residency classification

6.10.1 Incidence Date Determination

PCS–MCR follows IARC hierarchy with registry-specific refinement as follows:

6.10.1.1 Date of first physician consultation for cancer-related symptoms (date of admission or outpatient consultation), provided malignancy is later confirmed
6.10.1.2 Date of histological confirmation
6.10.1.3 Date of radiologic confirmation (where appropriate)
6.10.1.4 Date of first hospital admission or treatment
6.10.1.5 Date of death (DCO cases)

The "first physician consult" date refers to the earliest documented admission or outpatient consultation where suspicion of malignancy was recorded in the diagnosis field.

DECISION RULE 6-F: FIRST CONSULT RULE

The first physician consult date may be used as incidence date only if subsequent documentation confirms malignancy consistent with IARC standards.

If malignancy is never confirmed → case remains pending and is excluded from incidence analysis.

The use of the first physician consultation date as the incidence date is consistent with IARC guidance when the consultation represents the first documented clinical encounter for symptoms later confirmed to be malignant. This approach allows the registry to approximate the earliest clinical recognition of the disease when diagnostic confirmation occurs later.

6.10.2 Date of Last Contact

Date of last contact is defined as the most recent date recorded in any consolidated cancer-related source document.

If death certificate data are present, date of death becomes the date of last contact.

This variable supports survival analysis and longitudinal updates.

6.11 Coding and Classification

Coding is performed only after record linkage and consolidation are completed.

Primary site (topography), morphology, behavior, basis of diagnosis, extent of disease, laterality, and site of distant metastasis are coded according to:

- ICD-O (current edition adopted by the registry)
- IARC multiple primary rules
- CanReg multiple primary implementation logic
- Registry-adopted coding guidelines (Annex: Coding Manual)

Multiple primary determination follows IARC multiple primary rules. Consistent with CanReg logic, each patient retains a single registry number while sequence numbers distinguish separate primary tumors.

Basis of diagnosis codes are assigned using the registry's adopted coding scheme aligned with IARC classifications.

Where stage is not explicitly documented, registrars may derive essential TNM stage using available clinical and imaging data, consistent with IARC guidance permitting stage derivation when adequately supported.

All coding decisions are subject to supervisory review prior to database finalization

6.12 Encoding

This section describes the procedure for entering validated cancer registry abstracts into the PCS–MCR registry database. Encoding is performed only after completion of record linkage, residency determination, eligibility classification, incidence date determination, and coding. The purpose of this step is to convert the finalized patient abstract into a structured electronic registry record that can be used for validation, statistical analysis, and reporting.

6.12.1 Encoding Procedure

Encoding is performed by the assigned Cancer Registrar using the approved registry software system. All data must be entered exactly as documented in the consolidated abstract and coded according to the applicable international classification standards adopted by the registry.

Step 1: Access Registry Encoding Interface

The cancer registrar logs into the registry database system and opens the encoding interface for new or updated patient abstracts.

Step 2: Enter Patient and Case Variables

The cancer registrar encodes the consolidated abstract into the registry database using the verified patient identifiers and coded variables. The following variables are entered or confirmed:

- Source Name
- Sex
- Marital Status
- Address
- Birthplace
- Race
- Basis of diagnosis
- Topography
- Morphology
- Behavior
- Stage or extent of disease
- Initial Treatment
- Vital Status
- Causes of Death (if applicable)
- Place of Death (if applicable)
- Incidence date
- Date of last contact

All entries must reflect the coded values determined during the coding stage.

Step 3: System Validation Checks

Upon entry, the registry software automatically applies built-in validation checks, including:

- mandatory field verification
- logical consistency checks
- range and format validation
- duplicate detection alerts

Step 4: Correction of Validation Errors

Records failing validation checks are automatically flagged by the system. The cancer registrar reviews the flagged fields, verifies the source documentation, and corrects any detected errors before proceeding.

If the discrepancy cannot be resolved by the cancer registrar, the case is escalated to the Registry Manager or Registry Director for review.

Step 5: Save Record to Master Registry Database

Once all validation checks have been satisfied, the encoded record is saved to the registry master database, where it becomes available for quality review and subsequent registry processing.

DECISION RULE 6-G: DATABASE ENTRY

Only records that have successfully completed the following registry workflow stages may be encoded into the registry database:

- Record linkage
- Residency Determination
- Eligibility Classification
- Coding
- Incidence date determination
- Date of last contact determination

Records that have not completed these stages shall not be entered into the registry database

All encoded records remain subject to subsequent registry quality review and validation procedures described in Section 6.14.

6.12.2 Encoding Quality Safeguards

To ensure accuracy and consistency of encoded registry records, the following safeguards shall be applied during the encoding process:

6.12.2.1 Source Verification Requirement

All variables entered into the registry database must correspond exactly to the coded values documented in the consolidated patient abstract. Registrars shall not modify clinical information during encoding unless a documented correction has been approved through the registry quality review process.

6.12.2.2 Duplicate Entry Prevention

Prior to saving a newly encoded record, the registrar shall confirm that the patient has not already been assigned a registry number through the record linkage and historical cross-check procedures described in Sections 6.5 and 6.6.

6.12.2.3 Coding Consistency Verification

The registrar shall verify that the encoded topography, morphology, behavior, and basis of diagnosis correspond to the finalized codes assigned during the coding stage.

6.12.2.4 Escalation of Unresolved Discrepancies

If inconsistencies or missing information are identified during encoding that cannot be resolved through available source documentation, the case shall be escalated to the Registry Manager for verification prior to database entry.

6.12.2.5 System Validation Compliance

No record may be finalized in the registry database unless all mandatory system validation checks have been successfully satisfied.

These safeguards ensure that encoded records accurately reflect the validated patient abstract and maintain the integrity of the registry master database.

6.13 Registry Number Assignment

Each patient is assigned a unique MCR Registry Number. This number is patient-based and remains constant across multiple primaries.

Upon encoding into CanReg, an accession number is generated. Multiple primaries are distinguished through sequence numbers while retaining the same patient identifier.

This structure ensures traceability, compatibility with international registry software systems, and prevention of duplicate counting.

6.14 Quality Control and Validation

The quality control process is integrated throughout the registration lifecycle and is mandatory for all submitted cases. It involves the use of internationally recognized validation software, specifically the IARC/WHO CanReg4 (or subsequent official version) for running automated checks on data completeness, internal consistency, and logical validity. Coding accuracy is cross-checked against the International Classification of Diseases for Oncology, Third Edition (ICD-O-3) and the latest version of the IARC/IACR Multiple Primary Rules, 2020 Edition (or subsequent official revision) to ensure that the registry data is comparable to international standards.

Validation checks include duplicate detection, missing variable review, logical consistency checks including sex-site validation, verification of impossible date sequences, and review of basis of diagnosis assignments.

The registry monitors performance indicators consistent with IARC quality benchmarks, including Morphologically Verified percentage (MV%), Death Certificate Only percentage (DCO%), proportion of unknown primary site, and proportion of unknown age.

All inconsistencies are resolved prior to analytical processing.

These procedures support the registry's classification as a high-quality population-based cancer registry and its inclusion in *Cancer Incidence in Five Continents*.

6.14.1 Cancer Registrar Self-Check

Before finalizing encoding, the registrar reviews:

- completeness of identifiers
- consistency of diagnosis and morphology
- presence of incidence date
- treatment information

6.14.2 Senior Cancer Registrar Validation

Senior Cancer Registrar performs:

- duplicate detection
- logical consistency checks (e.g. sex and primary site incompatibility)
- coding verification
- death certificate only rate review

6.14.3 Automated Registry Validation

Validation routines include:

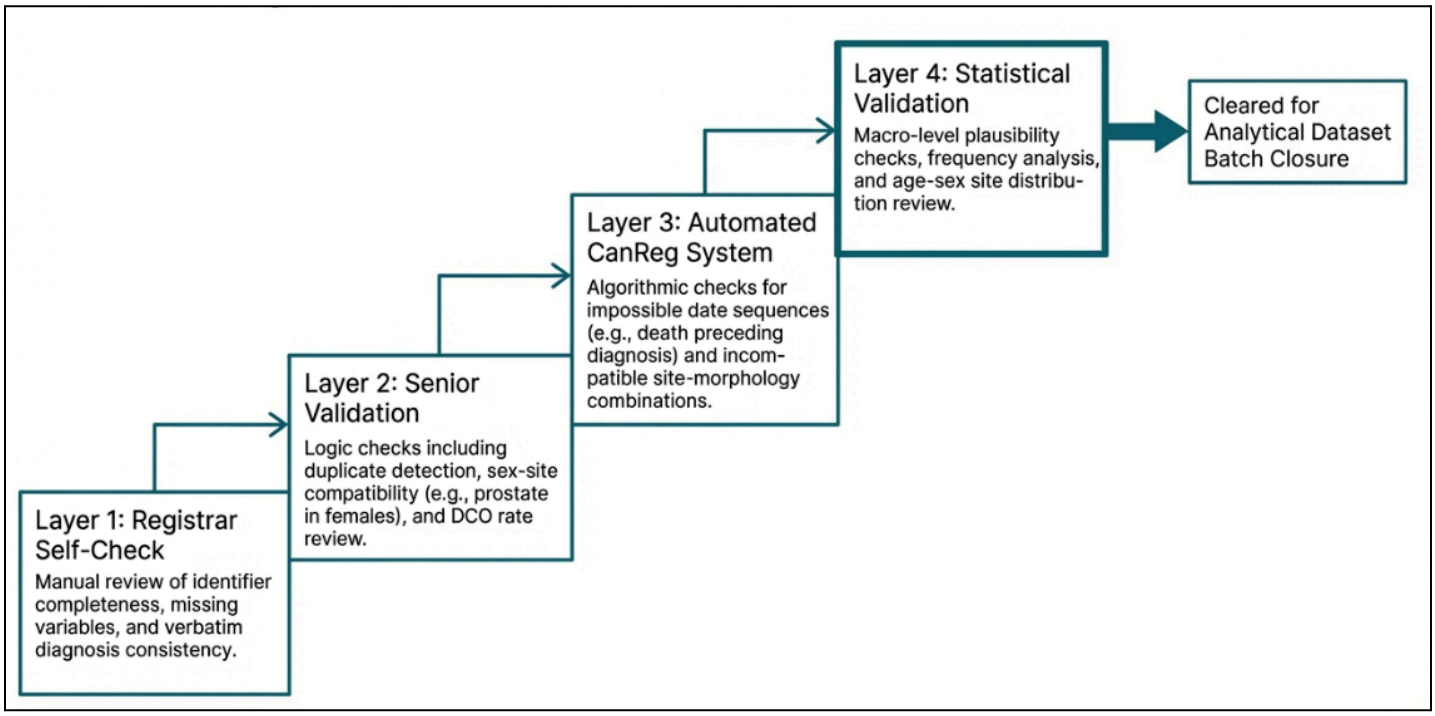
- impossible date sequences
- incompatible site–morphology combinations
- duplicate registry numbers

6.14.4 Statistical Validation

Prior to analysis, the Statistician performs:

- frequency checks
- site distribution review
- age-sex plausibility checks

Figure 10. Quality Control and Validation



6.15 Statistical Analysis and Reporting

Statistical analysis is conducted using resident, eligible cases only.

The registry calculates crude rates, age-specific rates, and age-standardized rates using approved standard populations.

Analytical methods are documented to ensure reproducibility. All official statistical outputs undergo review by the Registry Director and approval by institutional leadership prior to dissemination.

6.16 Analytical Dataset Finalization and Batch Closure

Upon completion of consolidation, coding, validation, and analysis for a defined reporting period, the Registry Director declares the Analytical Dataset Finalization Date.

This date establishes the version of the dataset used for official reporting.

Subsequent updates to historical cases may occur during later collection cycles. However, published reports reflect the dataset as finalized on the declared date, ensuring reproducibility and auditability.

6.17 Record Retention and Archiving

Confirmed registry records are permanently retained as official population-based cancer registry data.

Suspicious or unconfirmed records are retained for up to five years after batch closure unless malignancy is confirmed earlier. Archiving follows national records management regulations.

Digital data are backed up regularly on secure registry servers. Finalized datasets corresponding to reporting periods are preserved for reproducibility.

6.18 Passive Follow-up and Vital Status Determination

While active patient follow-up is not a routine function, the registry conducts passive follow-up to determine the vital status (alive/dead) and date of death for registered cases. This may be achieved through systematic, periodic linkage with external data sources such as the Philippine Statistics Authority (PSA) Civil Registry and other approved national/local death records, such as the local civil registries in full compliance with Section 7. This process is essential for the calculation of cancer survival statistics.

6.19 Operational Continuity and Contingency Management

PCS-MCR maintains procedures to ensure continuity of registry operations during events that may disrupt normal activities such as, but not limited to, force majeure, pandemics or public health emergencies, system or database failure.

Contingency measures include:

- Off-site data backup of registry databases
- Secure storage of physical collection forms
- Temporary suspension of field collection
- Remote data processing where feasible
- Restoration of registry database from backup copies
- Incident documentation and recovery report.

7. DATA SECURITY, CONFIDENTIALITY, AND ACCESS CONTROL

7.1 Legal and Ethical Framework

PCS–MCR processes personal and health information under the lawful mandate provided by:

- Republic Act No. 11215 (National Integrated Cancer Control Act)
- Republic Act No. 10173 (Data Privacy Act of 2012)
- Commonwealth Act No. 3573
- Relevant Department of Health issuances
- International confidentiality principles issued by IARC and IACR

Cancer registration is conducted as a public health function. Data collected are used exclusively for surveillance, epidemiologic analysis, cancer control planning, and authorized research.

All registry personnel are required to adhere to strict confidentiality obligations consistent with national law and international registry practice.

7.2 Categories of Data Processed

The registry processes data categorized into three tiers, each with distinct access and release controls:

7.2.1 Tier 1: Identifiable Individual Level Data

Includes Direct Identifiers (Name, exact Address, Patient ID, etc.). Access is strictly limited to Authorized Personnel (7.3).

7.2.2 Tier 2: De-Identified Individual-Level Data

Includes Indirect Identifiers (Age, Sex, City/Municipality of Residence, Date of Diagnosis/Death, etc.) but excludes all Direct Identifiers. This is the minimum standard for individual-level data release for approved research purposes.

7.2.3 Tier 3: Aggregated Statistical Data

Data released at the group or population level (e.g., incidence rates by age group, cancer type), fully anonymized with no potential for individual identification.

The process for de-identification must adhere to the Data Privacy Act of 2012 and the IACR Guidelines for Confidentiality.

7.3 Access Control and Role-Based Permissions

Access to registry data is restricted based on defined roles and responsibilities.

Cancer Registrars engaged in case ascertainment and abstraction are granted access to identifiable information strictly for operational purposes.

Senior Cancer Registrars are granted elevated access rights for record linkage, correction of identifiers, coding finalization, and quality control review.

The Statistician/Data Analyst is granted access only to de-identified datasets for analytical purposes.

The Registry Director retains authority to approve access levels and may suspend or revoke access in cases of suspected non-compliance.

Where digital systems support role-based access controls, permissions are configured accordingly. Where interim systems do not support granular access restrictions, compensatory controls are implemented, including activity logging, version history monitoring, and controlled file storage.

Access privileges are reviewed periodically and adjusted as needed.

7.4 Confidentiality Agreements and Personnel Obligations

All registry personnel must execute a formal Confidentiality Agreement prior to being granted access to identifiable registry data.

Confidentiality obligations remain in force beyond termination of employment or engagement.

Personnel shall disclose any potential conflicts of interest that may affect objectivity in registry operations.

Violation of confidentiality policies may result in suspension of access privileges, administrative action, or referral under applicable laws.

Records of executed confidentiality agreements are maintained in personnel files.

7.5 Technical Safeguards

Technical safeguards are implemented to ensure the integrity and confidentiality of the digital registry data. These include:

- Secure server-based data storage
- Regular data backup procedures
- Controlled upload and download of datasets
- Version history monitoring
- Role-based access control in current and future registry platforms
- Encryption where supported by system infrastructure (e.g. transport and storage)
- Restricted external data transfer

Digital registry data are stored on secured PCS servers. Backup copies are maintained to prevent data loss and ensure continuity of operations. When migrating between registry software platforms, data integrity verification procedures are implemented to ensure no loss, corruption, or unauthorized alteration of records.

Compliance with these safeguards is verified through quarterly reviews of all system access and activity logs by the Registry Manager and Registry Director. Furthermore, the registry's data system is subjected to a formal, documented annual security/penetration assessment by an independent, authorized IT security professional.

7.6 Physical Safeguards

Physical registry records and historical paper-based materials are stored at the PCS-MCR office. Physical safeguards protect hard copy records and hardware. These include secure storage, restricted access areas, and video surveillance.

Access to physical storage areas is restricted to authorized personnel. Archived records are retained in accordance with national records management regulations.

7.7 Data Sharing and Inter-Registry Collaboration

PCS–MCR may share registry data under defined conditions consistent with its public health mandate.

Data sharing occurs in the following contexts:

1. Transfer of resident cases to other population-based cancer registries
2. Contribution to national cancer surveillance
3. Submission to international surveillance initiatives (e.g., IARC, CI5)
4. Approved research collaborations

Data shared are limited to:

- Residents of the receiving registry's catchment area
- De-identified datasets for research
- Aggregated statistical data for publication

Data are shared only after record linkage and duplicate resolution have been completed.

PCS–MCR retains a local copy of all data shared.

Formal Data Sharing Agreements may be executed to define scope, permitted use, confidentiality obligations, and security standards.

7.8 Data Breach and Incident Response

Any suspected or confirmed data breach shall be immediately reported to:

- The Registry Director
- The PCS Data Privacy Officer

The Data Privacy Officer shall assess the incident and determine reporting obligations in accordance with Republic Act No. 10173 and related regulations.

Access privileges may be suspended pending investigation.

Corrective and preventive actions shall be documented and implemented.

7.9 Data Retention and Destruction

Confirmed registry data are permanently retained as part of the official population-based cancer registry record. Suspicious or unconfirmed records are retained for up to five years following batch closure unless malignancy is confirmed earlier.

Data destruction, where permitted, shall be conducted securely and documented. Retention practices comply with national records management policies.

7.10 Audit and Monitoring

Data protection compliance is subject to periodic internal review.

Registry operations may be subject to:

- Institutional audit
- DOH review
- IARC evaluation
- External accreditation review

All required documentation, including access logs, quality control records, and confidentiality agreements, shall be made available during authorized audits.

8. MONITORING, PERFORMANCE INDICATORS, AND CONTINUOUS IMPROVEMENT

8.1 Purpose of Monitoring and Measurement

PCS–MCR implements structured monitoring and performance evaluation mechanisms to ensure that cancer registration activities meet internationally accepted standards of data quality, completeness, validity, comparability, and reproducibility.

Performance monitoring aligns with:

- IARC Technical Publication No. 43
- IARC Manual for Cancer Registry Personnel
- AFCRN Standard Procedures
- Cancer Incidence in Five Continents (CI5) quality criteria
- ISO 9001 principles on monitoring, measurement, and continual improvement

Monitoring activities are conducted throughout the registration cycle and formally reviewed prior to analytical dataset finalization.

8.2 Core Registry Performance Indicators and Target Benchmarks

PCS–MCR adopts the Core Registry Performance Indicators as defined by IARC/IACR to assess the completeness, validity, and quality of its data. Each indicator is assigned a minimum performance target, which must be reviewed during the annual SOP review (10.4) and reported in the Annual Registry Report (4.4).

8.2.1 Morphologically Verified Percentage (MV%)

Definition: The proportion of all registered cases with histological or cytological confirmation (Basis of Diagnosis codes 5, 6, 7, or 8). This indicator reflects diagnostic validity and adherence to pathology confirmation standards.

Target Benchmark: ≥ 80%

8.2.2 Death Certificate Only Percentage (DCO%)

Definition: The proportion of all registered cases for which the only source of information is a death certificate (Basis of Diagnosis code 0). This indicator reflects completeness of case ascertainment and adequacy of trace-back procedures.

Target Benchmark: < 5%

8.2.3 Proportion of Cases with Unknown Age

Definition: The proportion of registered cases where the age of the patient is unknown or unverified. This indicator reflects completeness of core demographic variables.

Target Benchmark: ≤ 1%

8.2.4 Mortality-to-Incidence Ratio (M:I)

Definition: The ratio of cancer mortality to cancer incidence for a defined population and period. This indicator provides a general measure of case ascertainment completeness and comparability with international estimates. Extremely high ratios may indicate incomplete case registration or delayed case capture.

Target Benchmark: Values should be consistent with expected national or regional patterns.

These indicators are calculated for each finalized reporting period and reviewed prior to release of official registry reports.

8.3 Internal Validation and Logical Consistency Review

In addition to summary indicators, PCS–MCR conducts structured internal validation processes.

These include:

- Duplicate detection prior to encoding
- Review of inconsistent sex-site combinations
- Logical verification of TNM staging against metastatic site
- Review of impossible date sequences (e.g., death preceding diagnosis)
- Verification of basis of diagnosis coding
- Review of multiple primary determination consistency

Validation procedures are applied prior to final coding and again prior to statistical analysis.

All detected inconsistencies are documented and corrected before analytical dataset finalization.

8.4 Review and Oversight Mechanisms

Quality indicators and validation outcomes are reviewed by:

- Registry Manager
- Registry Director

Performance summaries are included in the Registry Director's bi-monthly report to the President and Board of Trustees.

Where trends suggest deviations from acceptable international benchmarks, corrective measures are initiated.

8.5 Corrective and Preventive Actions

The registry maintains a formal Corrective and Preventive Action (CAPA) Log or system (as defined in Section 3) to manage all identified non-conformities (from internal audits, quality checks, or external evaluations) and opportunities for improvement. For all high-impact or recurring non-conformities, a formal Root Cause Analysis (RCA) must be documented, approved by the Registry Manager and Registry Director, and tracked to verify the effectiveness of the corrective action taken to prevent recurrence.

Table 6. Risk Register

Risk	Likelihood	Impact	Mitigation
Loss of source records	Medium	High	Multi-source ascertainment
Duplicate records	Medium	Medium	Record linkage procedures
Data entry errors	Medium	Medium	Senior registrar validation
Software failure	Low	High	Regular database backup
Natural disasters	Low	High	Off-site storage

8.6 Continuous Improvement

PCS–MCR recognizes continuous improvement as an integral component of its operations.

Improvements may arise from:

- Internal review findings
- DOH feedback
- IARC evaluation visits
- Participation in CI5 submissions
- Migration to improved digital platforms
- Inter-registry collaboration

Operational changes resulting from improvement initiatives are documented and, where necessary, incorporated into revised procedures.

8.7 External Evaluation and International Benchmarking

PCS–MCR has been recognized as a high-quality population-based cancer registry and has contributed data to multiple volumes of *Cancer Incidence in Five Continents*.

Participation in CI5 submission requires compliance with stringent IARC data quality criteria.

Registry processes remain subject to:

- IARC technical review
- Department of Health oversight
- Institutional audit

Such external evaluation mechanisms reinforce the registry's commitment to international standards.

8.8 Documentation and Records of Monitoring

The registry maintains documented records of:

- Quality indicator calculations
- Validation reports
- Corrective action documentation
- Finalized analytical dataset declarations

These records are retained in accordance with registry retention policy and made available during authorized audits.

9. DATA RELEASE, PUBLICATION, AND RESEARCH ACCESS

9.1 Principles Governing Data Release

PCS–MCR recognizes that cancer registry data are collected under statutory public health authority and are entrusted to the registry for surveillance, planning, and research purposes.

Release of registry data shall be governed by the following principles:

- Protection of patient confidentiality
- Compliance with Republic Act No. 10173 (Data Privacy Act)
- Consistency with Republic Act No. 11215
- Adherence to IARC/IACR confidentiality guidelines
- Preservation of scientific integrity and reproducibility

Where cases are identified as residents of another population-based cancer registry catchment area, PCS–MCR may coordinate with the appropriate registry for case transfer to ensure accurate national cancer surveillance coverage.

No identifiable registry data shall be publicly disclosed.

All data releases must follow the procedures outlined in this section.

9.2 Categories of Data That May Be Released

PCS–MCR may release data in the following formats:

9.2.1 Aggregated Statistical Data

Aggregated data presented in tabular or summarized form that contain no identifiable information.

This includes:

- Incidence rates
- Mortality summaries
- Age-standardized rates
- Distribution by sex, site, or year

Aggregated statistical releases do not require individual-level data review provided no small-cell risk of re-identification exists.

9.2.2 De-Identified Individual-Level Data

De-identified datasets may be released for approved research purposes.

Such datasets shall exclude:

- Names
- Exact addresses
- Contact numbers
- Hospital numbers
- Direct identifiers

Indirect identifiers shall be reviewed to minimize re-identification risk.

The Statistician/Data Analyst shall prepare de-identified datasets, subject to approval by the Registry Director.

9.2.3 Inter-Registry Data Exchange

PCS–MCR may share resident cases with other Population-Based Cancer Registries for the purpose of:

- Eliminating duplication
- Ensuring completeness
- Harmonizing national cancer surveillance

Only cases belonging to the receiving registry's defined catchment area shall be transferred.

Data sharing shall occur only after record linkage and duplicate resolution.

A local copy of shared data shall be retained.

Formal Data Sharing Agreements may be executed to define scope, permitted use, and confidentiality safeguards.

9.3 Data Request and Approval Process

All requests for data release (Tier 2 and Tier 3) must be submitted via the controlled PCS–MCR Data Release Request Form. The request undergoes a formal, documented review by the Registry Director to assess scientific merit, ethical compliance, and data security risk.

Approval for the release of Tier 2 (De-Identified Individual-Level Data) is contingent upon the execution of a legally binding Data Transfer Agreement (DTA) between PCS–MCR and the requesting party. The DTA must explicitly define the permitted scope of data use, the requirements for data security and storage, a data use expiry date, and a clause mandating data destruction upon project completion.

Requests involving the release of Tier 1 (Identifiable Individual Level Data) shall require:

- Scientific justification
- Ethical clearance where applicable
- Data protection safeguards

Approval authority shall follow this hierarchy:

1. Registry Director – technical review
2. Cancer Registry Committee – review for policy-level releases when required
3. President of the Philippine Cancer Society – final approval

No dataset shall be released without documented approval.

The registry operates under a Service Level Agreement (SLA) target for data request processing, aiming to provide an initial review decision to the applicant within 30 working days of receiving a complete submission.

9.4 Publication and Authorship Policy

All official statistical releases of PCS–MCR must be reviewed by:

- The Registry Director
- The Cancer Registry Committee
- The President of the Philippine Cancer Society

Where appropriate, the Cancer Registry Committee may review major publications or strategic reports.

Researchers using registry data must acknowledge PCS–MCR as the data source.

Authorship eligibility for PCS–MCR personnel shall follow recognized academic authorship standards and institutional policy.

Draft manuscripts using registry data may be subject to registry review to ensure:

- Accurate interpretation
- Proper methodology
- Correct citation of registry data

PCS–MCR reserves the right to decline endorsement of analyses that misrepresent registry data.

9.5 Restrictions on Data Use

Data released by PCS–MCR:

- Shall not be used for commercial marketing purposes
- Shall not be used to identify individual patients
- Shall not be redistributed without written permission
- Shall not be used in a manner inconsistent with approved objectives

Any violation of data use conditions may result in revocation of access and possible legal action.

9.6 Confidentiality in Publications

No publication or presentation may include:

- Individual patient identifiers
- Information enabling identification of specific individuals
- Small-cell data that risk re-identification

Minimum cell suppression rules may be applied where necessary.

9.7 Retention of Released Data Records

PCS–MCR shall maintain documentation of:

- Data requests
- Approval decisions
- Datasets released
- Correspondence related to release
- Signed data sharing or use agreements

These records form part of registry governance documentation and are retained in accordance with institutional retention policy.

9.8 Contribution to International Reporting

PCS–MCR may submit validated datasets to international initiatives, including IARC-coordinated publications such as *Cancer Incidence in Five Continents*.

Such submissions shall comply with international formatting, validation, and confidentiality standards.

Data included in international submissions must correspond to the Analytical Dataset Finalization Date for the relevant reporting period.

10. DOCUMENT CONTROL, REVIEW, AND REVISION MANAGEMENT

10.1 Purpose of Document Control

This section establishes the framework for managing all documentation essential to PCS–MCR operations. The SOP and all referenced controlled documents shall be managed within a designated, centralized Document Management System (DMS) (physical or electronic). The DMS serves to ensure that all personnel have access to the correct and current version of documentation, prevent the unintended use of obsolete documents, and provide a clear audit trail for all changes (10.5).

10.2 Ownership and Custodianship

The Registry Director is the document owner of this SOP and shall be responsible for:

- Initiating revisions
- Reviewing proposed amendments
- Ensuring alignment with updated legal, regulatory, or international standards
- Submitting revised versions for institutional approval

The Cancer Registry Committee may review proposed revisions prior to approval when technical or policy-level modifications are involved. The President of the Philippine Cancer Society holds final approval authority for this SOP.

10.3 Version Identification and Approval

Each version of this SOP shall include:

- Version number
- Date of approval
- Effective date
- Summary of revisions
- Approval signatures

A Document Control Page shall be maintained at the beginning of the SOP to record:

- Version history
- Description of changes
- Approval authority
- Date of implementation

No revised version shall take effect without documented approval.

10.4 Review Cycle

This SOP and its Annexes shall be formally reviewed at least once every twelve (12) months (Review Date - see Control Item Table). The review process is cross-functional and must include documented input and approval from:

- The Statistician / Data Analyst
- The Data Protection Oversight
- The Registry Manager
- The Registry Director
- The Cancer Registry Committee
- The President

This multi-disciplinary review ensures continued suitability, adequacy, and effectiveness of the SOP with respect to internal operations, external mandates, and international standards.

10.5 Amendment Procedures

Proposed amendments may be initiated by:

- Registry Manager
- Registry Director
- Cancer Registry Committee
- President of PCS

Amendments shall be documented in writing and must specify:

- Section to be revised
- Rationale for change
- Impact on registry operations

Minor procedural clarifications that do not alter policy may be incorporated through controlled updates.

Policy-level changes require review by the Cancer Registry Committee and approval by the President.

10.6 Distribution Control

The current approved version of this SOP shall be:

- Stored in the official PCS–MCR document repository
- Made accessible to all registry personnel
- Provided to institutional oversight bodies upon request

Electronic copies shall be maintained in secure internal storage.

Printed copies, if issued, shall be marked as “Controlled Copy.”

Uncontrolled copies must clearly indicate that they are not subject to automatic updates.

10.7 Obsolete Documents

Superseded versions of this SOP shall be:

- Archived with version labeling
- Marked as “Obsolete”
- Retained for historical and audit reference

Obsolete versions shall not be used for operational purposes.

10.8 Alignment with Annexes and Referenced Documents

Annexes referenced in this SOP form part of the controlled document system.

Annexes may include:

- Organizational Structure
- Data Collection Forms
- Coding Manuals
- Reportable Tumor List
- Data Release Request Form
- Confidentiality Agreement Template
- Coding Code Lists

Updates to annexes that do not alter core policy may be implemented without revising the entire SOP, provided the document control page reflects such updates.

Annex A: Philippine Cancer Society - Manila Cancer Registry Confidentiality Protocol

Philippine Cancer Society

Trunk Line: 8734-2126
Patient Services: Local 105, DL/ Telefax 8735-2707
Education & Information /Cancer Registry: Local 108
Resource Generation: Local 106, DL /Telefax 8734-2127
Executive Director's Office: 8733-3486
Mobile: 0917-576-2909
Email: pcsi@philcancer.org.ph
Website: www.philcancer.org.ph

310 San Rafael Street, San Miguel, City of Manila 1005, Philippines

CONFIDENTIALITY PROTOCOL
Philippine Cancer Society – Manila Cancer Registry

Purpose

This protocol protects personal and medical information collected by the Philippine Cancer Society – Manila Cancer Registry (PCS–MCR) in line with the Philippine Data Privacy Act of 2012 (RA 10173) and the IARC/IACR Guidelines on Confidentiality for Population-Based Cancer Registration. It governs collection, processing, storage, analysis, reporting, and sharing of registry data.

Scope

Applies to all PCS–MCR personnel, trainees, contractors, and partner institutions that access identifiable registry data across all sources (hospitals, pathology laboratories, civil registry/vital statistics, and other reporting units).

Guiding Principles

1. ***Confidentiality:*** personally identifiable information (PII) is strictly protected.
2. ***Legitimate purpose:*** identifiable data are used only for cancer surveillance, control, and approved research.
3. ***Minimum necessary:*** collect and process only identifiers essential for accurate linkage and de-duplication.
4. ***Security by design:*** administrative, technical, and physical safeguards are maintained proportionate to risk.
5. ***Anonymity in outputs:*** publications and shared datasets are de-identified and aggregated.

Data Access and Handling

1. Access to identifiable data is restricted to authorized staff who sign Confidentiality and Data Use Agreements.
2. Electronic data reside on password-protected devices within PCS premises with role-based access; removable media are encrypted.
3. Paper records are stored in restricted areas.
4. Transmission for verification or reporting uses encryption; identifiers are removed when not required.

Data Release and Sharing

Identifiable data are not released externally without written approval of the Registry Head and, where applicable, a data-sharing agreement compliant with RA 10173 and NPC Circulars. External requests are reviewed by the PCS–MCR Registry Committee. Only de-identified/aggregated datasets are provided and limited to the

Philippine Cancer Society

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Patient Services: Local 105, DL/ Telefax 8735-2707
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Resource Generation: Local 106, DL /Telefax 8734-2127
Executive Director's Office: 8733-3486
Mobile: 0917-576-2909
Email: pcsi@philcancer.org.ph
Website: www.philcancer.org.ph

310 San Rafael Street, San Miguel, City of Manila 1005, Philippines

stated purpose. Publications must avoid any possibility of re-identification (for example, small-cell suppression). The registry is acknowledged in any outputs.

Retention and Disposal

Records are retained only as long as necessary for surveillance and quality assurance. Disposal of identifiers follows documented procedures (secure deletion/shredding) and is recorded.

Incident Response

Any suspected or actual breach of confidentiality is reported immediately to the Registry Head. Incidents are contained, investigated, documented, and, when required by law, notified to the National Privacy Commission and affected data subjects.

Legal and Standards Alignment

- Republic Act No. 11215 (National Integrated Cancer Control Act) provisions on cancer registration.
- Republic Act No. 10173 (Data Privacy Act of 2012) and its IRR;
- National Privacy Commission issuances on data sharing and breach notification.
- IARC/IACR Guidelines on Confidentiality for Population-Based Cancer Registration (2004) and IARC Technical Publication No. 43 (2014).

Annex B: Philippine Cancer Society - Data Release Request and Agreement Form

Philippine Cancer Society

Trunk Line: 8734-2126
Patient Services: Local 105, DL/ Telefax 8735-2707
Education & Information /Cancer Registry: Local 108
Resource Generation: Local 106, DL /Telefax 8734-2127
Executive Director's Office: 8733-3486
Mobile: 0917-576-2909
Email: pcsi@philcancer.org.ph
Website: www.philcancer.org.ph

310 San Rafael Street, San Miguel, City of Manila 1005, Philippines

DATA RELEASE REQUEST AND AGREEMENT FORM

Philippine Cancer Society – Manila Cancer Registry

Purpose

This form governs the request and release of data from the Philippine Cancer Society–Manila Cancer Registry (PCS–MCR). It ensures compliance with the Data Privacy Act of 2012 (RA 10173), the IARC/IACR Guidelines on Confidentiality for Population-Based Cancer Registration, and PCS internal data protection and ethical standards.

1. Applicant Information

Name of Applicant / Institution:	
Position / Affiliation:	
Address:	
Email / Phone:	

2. Purpose of Data Request

☐Research ☐Policy / Program Planning ☐Education ☐Other (specify): _____

Title or description of study/project: _____
Intended data use / objectives: _____
Expected outputs or publications: _____

3. Data Requested

Specify variables or data level requested (e.g., aggregated, anonymized individual records, geographic coverage, years of diagnosis).

Data description: _____
Time period: _____
Format requested: ☐Excel ☐CSV ☐PDF ☐Other: _____

4. Terms and Conditions

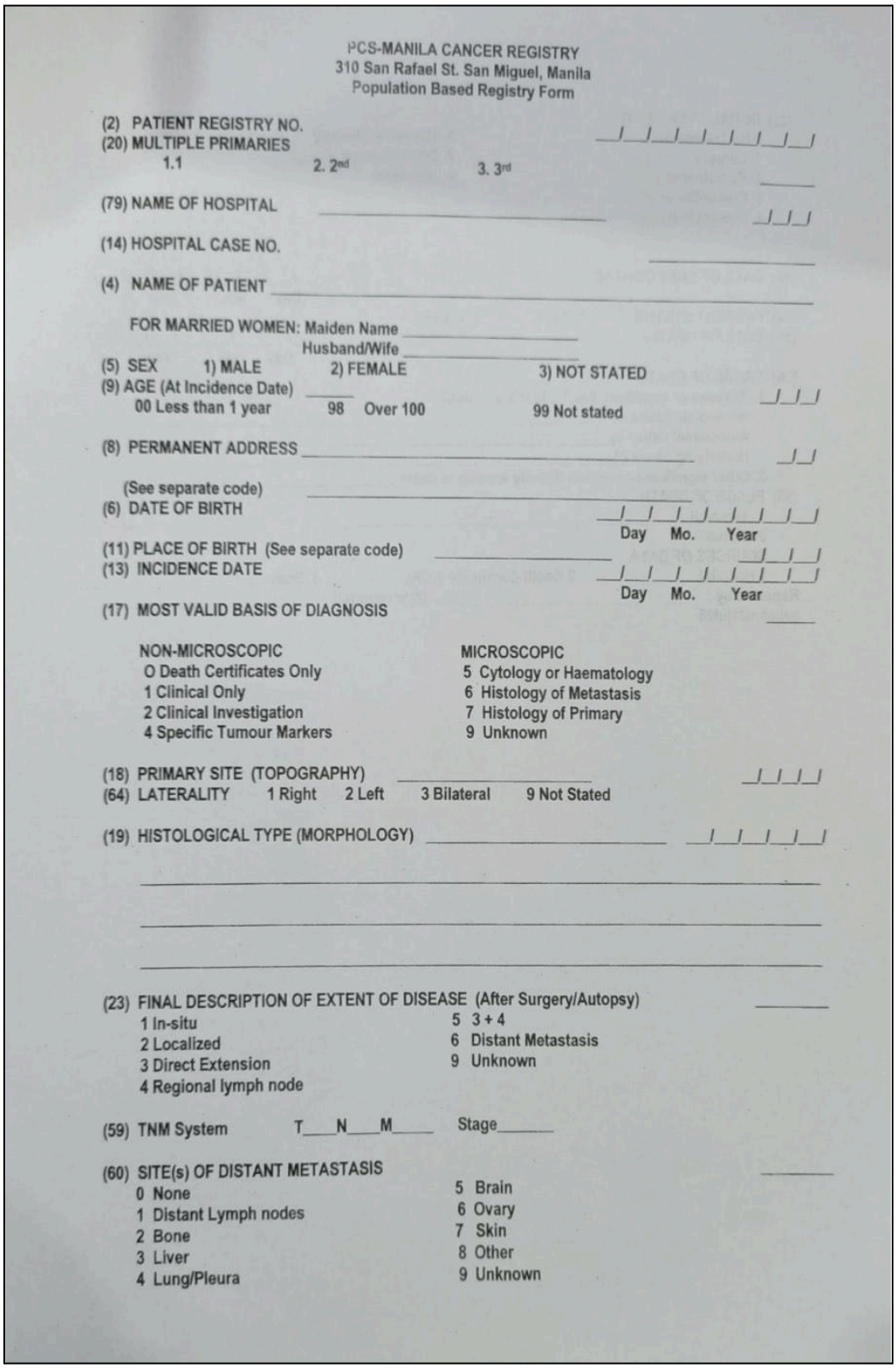
4.1. Data shall be used solely for the approved purpose and shall not be shared with third parties.
4.2. The applicant shall ensure no attempt is made to identify individuals or institutions from the data provided.
4.3. All publications or reports using registry data must acknowledge PCS–MCR as the data source.
4.4. The applicant agrees to implement safeguards to protect data confidentiality and security.
4.5. The registry reserves the right to deny, limit, or revoke access if misuse is detected.
4.6. A summary of outputs or publications using the data must be submitted to PCS–MCR upon completion.

5. Approval and Authorization

Requested by:	Signature / Date: _____
Reviewed by (Registry Head):	Signature / Date: _____
Approved by (PCS President / DPO):	Signature / Date: _____

Note: Only de-identified and aggregated data are released. Requests for individual-level or potentially identifiable data require Ethics Committee approval and a Data Sharing Agreement (DSA).

Annex C: Philippine Cancer Society - Manila Cancer Registry Paper Abstract Form



PCS-MANILA CANCER REGISTRY
310 San Rafael St. San Miguel, Manila
Population Based Registry Form

(2) PATIENT REGISTRY NO. __/__/__/__/__/__/__/__/__/__/
(20) MULTIPLE PRIMARIES
1.1 2. 2nd 3. 3rd _____

(79) NAME OF HOSPITAL _____ __/__/__/

(14) HOSPITAL CASE NO. _____

(4) NAME OF PATIENT _____

FOR MARRIED WOMEN: Maiden Name _____
Husband/Wife _____

(5) SEX 1) MALE 2) FEMALE 3) NOT STATED
(9) AGE (At Incidence Date) _____ __/__/__/
00 Less than 1 year 98 Over 100 99 Not stated

(8) PERMANENT ADDRESS _____ __/__/
(See separate code) _____

(6) DATE OF BIRTH __/__/__/__/__/__/__/__/__/__/
Day Mo. Year

(11) PLACE OF BIRTH (See separate code) _____ __/__/__/
(13) INCIDENCE DATE __/__/__/__/__/__/__/__/__/__/
Day Mo. Year

(17) MOST VALID BASIS OF DIAGNOSIS _____

NON-MICROSCOPIC	MICROSCOPIC
0 Death Certificates Only	5 Cytology or Haematology
1 Clinical Only	6 Histology of Metastasis
2 Clinical Investigation	7 Histology of Primary
4 Specific Tumour Markers	9 Unknown

(18) PRIMARY SITE (TOPOGRAPHY) _____ __/__/__/__/
(64) LATERALITY 1 Right 2 Left 3 Bilateral 9 Not Stated

(19) HISTOLOGICAL TYPE (MORPHOLOGY) _____ __/__/__/__/__/__/

_____

_____

_____

(23) FINAL DESCRIPTION OF EXTENT OF DISEASE (After Surgery/Autopsy) _____

1 In-situ	5 3 + 4
2 Localized	6 Distant Metastasis
3 Direct Extension	9 Unknown
4 Regional lymph node	

(59) TNM System T___N___M____ Stage_____

(60) SITE(s) OF DISTANT METASTASIS _____

0 None	5 Brain
1 Distant Lymph nodes	6 Ovary
2 Bone	7 Skin
3 Liver	8 Other
4 Lung/Pleura	9 Unknown

(22) INITIAL TREATMENT

0 No Treatment
1 Surgery
2 Radiotherapy
3 Chemotherapy
4 Immunotherapy
5 Hormone Therapy
8 Other Therapy
9 Unknown

(85) DATE OF LAST CONTACT __/__/__/__/__/__/__/__/
Day Mo. Year

(24) PRESENT STATUS 1 Alive 2 Dead _____

(25) DATE OF DEATH __/__/__/__/__/__/__/__/
Day Mo. Year

(26) CAUSE OF DEATH

1. Disease or condition directly leading to death
   Immediate cause a)_____
   Antecedent cause b)_____
   Underlying cause c)_____
2. Other significant condition directly leading to death_____

(83) PLACE OF DEATH

Hospital _____ __/__/__/

00 Home

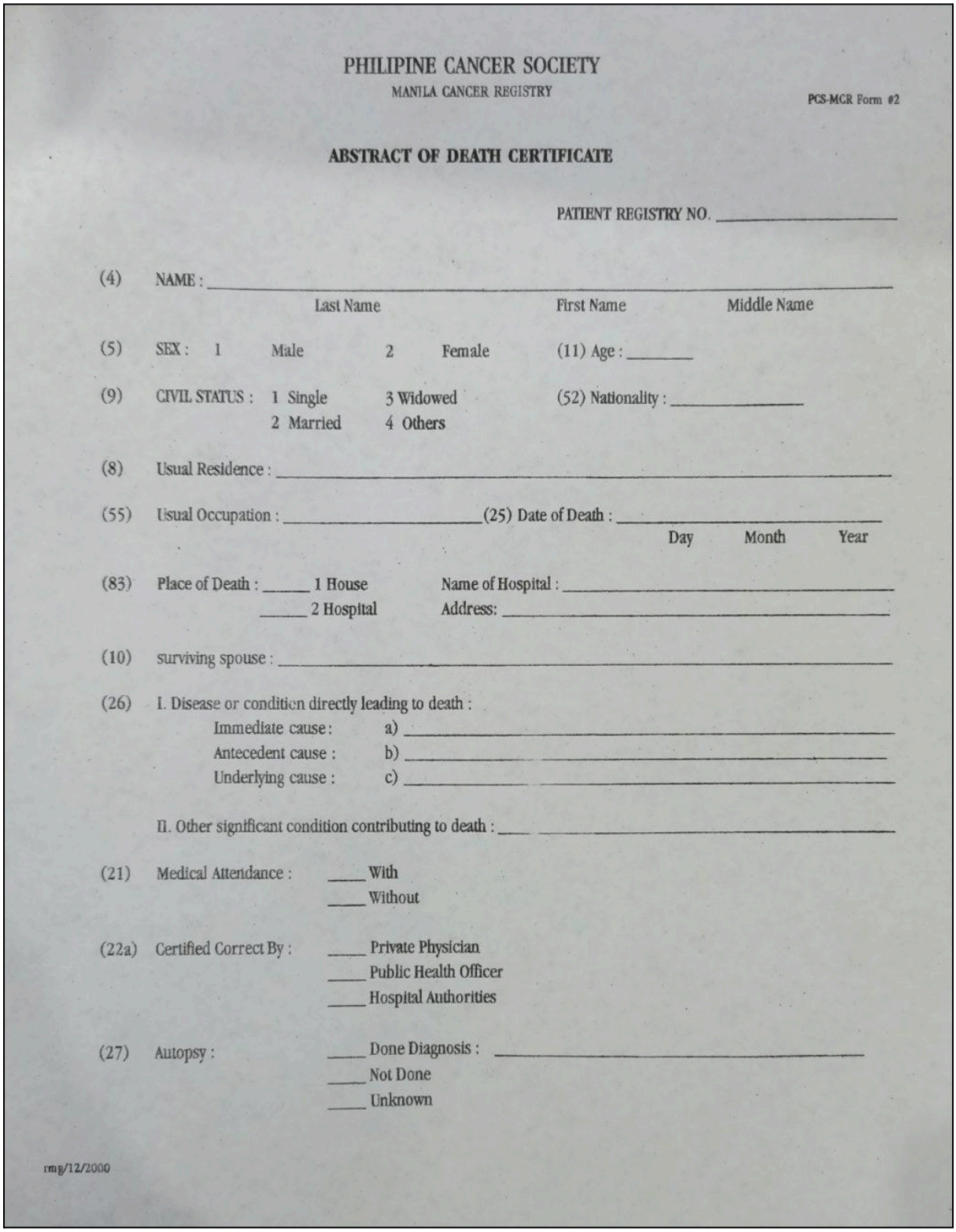
SOURCES OF DATA

1 Hospital 2 Death Certificate (LCR) 3 Both _____

Reported by : _____ Date reported _____

avl/esm21jul08

Annex D: Philippine Cancer Society - Manila Cancer Registry Abstract of Death Certificate Form



PHILIPINE CANCER SOCIETY
MANILA CANCER REGISTRY

PCS-MCR Form #2

ABSTRACT OF DEATH CERTIFICATE

PATIENT REGISTRY NO. _____

(4) NAME : _____
Last Name First Name Middle Name

(5) SEX : 1 Male 2 Female (11) Age : _____

(9) CIVIL STATUS : 1 Single 3 Widowed (52) Nationality : _____
2 Married 4 Others

(8) Usual Residence : _____

(55) Usual Occupation : _____ (25) Date of Death : _____
Day Month Year

(83) Place of Death : _____ 1 House Name of Hospital : _____
_____ 2 Hospital Address: _____

(10) surviving spouse : _____

(26) I. Disease or condition directly leading to death :
Immediate cause : a) _____
Antecedent cause : b) _____
Underlying cause : c) _____

II. Other significant condition contributing to death : _____

(21) Medical Attendance : ____ With
____ Without

(22a) Certified Correct By : ____ Private Physician
____ Public Health Officer
____ Hospital Authorities

(27) Autopsy : ____ Done Diagnosis : _____
____ Not Done
____ Unknown

rmg/12/2000

Annex E: Philippine Cancer Society - Manila Cancer Registry Nondisclosure Agreement

PHILIPPINE CANCER SOCIETY – MANILA CANCER REGISTRY
310 San Rafael St., San Miguel, 1005 Manila, Philippines
Contact Number Tel. no. (632) 734.2126 or 733.3486

NON-DISCLOSURE AGREEMENT (NDA)

Purpose

This Non-Disclosure Agreement (Agreement) is made between the Philippine Cancer Society – Manila Cancer Registry (PCS–MCR), represented by the Registry Head / Member of the Executive Action Team for Navigation and Registry, and the undersigned individual or organization (the Recipient). The purpose of this Agreement is to protect the confidentiality of all personal, sensitive personal, and proprietary information accessed during authorized engagements with PCS–MCR. This includes engagements with program developers, consultants, researchers, or collaborators. All obligations herein comply with the Data Privacy Act of 2012 (RA 10173), its Implementing Rules and Regulations, and the IARC/IACR Guidelines on Confidentiality for Population-Based Cancer Registration.

Definitions

1. **Personal Information** refers to any information, whether recorded in a material form or not, from which the identity of an individual is apparent or can be reasonably and directly ascertained by the entity holding the information, or when put together with other information would directly and certainly identify an individual.
2. **Sensitive Personal Information** refers to personal information:
   (1) About an individual's race, ethnic origin, marital status, age, color, and religious, philosophical, or political affiliations.
   (2) About an individual's health, education, genetic or sexual life, or to any proceeding for any offense committed or alleged to have been committed by such person, the disposal of such proceedings, or the sentence of any court in such proceedings.
   (3) Issued by government agencies peculiar to an individual, which includes, but is not limited to, social security numbers, previous or current health records, licenses or their denials, suspension or revocation, and tax returns; and
   (4) Specifically established by an executive order or an act of Congress to be kept classified.
3. **Confidential Information:** refers to all non-public information obtained from PCS–MCR, including registry data, medical records, software systems, algorithms, reports, operational procedures, and communications.

Obligations of the Recipient

The Recipient agrees to use confidential and personal information only for the specific purpose authorized by PCS–MCR; to maintain strict confidentiality and prevent unauthorized disclosure; to implement appropriate safeguards to protect all data accessed; to report any suspected or actual data breach immediately to the Registry Head; and to return or permanently delete all confidential materials upon completion of engagement or upon request.

Duration

This Agreement remains in effect throughout the Recipient's engagement and continues for five (5) years after termination, unless otherwise extended in writing by PCS–MCR.

Ownership of Data

All data, records, and materials accessed or generated remain the sole property of the Philippine Cancer Society – Manila Cancer Registry. The Recipient acquires no rights or ownership over such data and may only use it for authorized purposes.

Breach of Agreement

Any breach of this Agreement may result in termination of engagement, revocation of access, and legal action under applicable laws, including the Data Privacy Act of 2012. PCS–MCR reserves the right to seek remedies to prevent unauthorized disclosure or misuse.

Governing Law

This Agreement shall be governed by and construed in accordance with the laws of the Republic of the Philippines.

Acknowledgment and Acceptance

By signing below, the Recipient affirms that they have read, understood, and agree to comply with this Agreement and to uphold the confidentiality and integrity of all information received from PCS–MCR.

For the Philippine Cancer Society – Manila Cancer Registry (PCS–MCR)	**For the Recipient (program developers, consultants, researchers, or collaborators)**
Name:	Name:
Designation: Registry Head / Member, Executive Action Team for Navigation and Registry For and on behalf of the Philippine Cancer Society, under the supervision of the Board of Trustees	Designation:
Signature:	Signature:
Date:	Date:

Witnesses:

1.	Signature & Date:
2.	Signature & Date:

Annex F: Sample Data Sharing Agreement

DATA SHARING AGREEMENT

between
Philippine Cancer Society, Inc.
and
Name of Entity

I. PARTIES TO THE AGREEMENT

ENTITY RECEIVING DATA:
Philippine Cancer Society, Inc.
Appointed by the Department of Health as one of the institutions in charge of the Population-Based Cancer Registry in the Philippines.

CONTACT PERSON: [Name]
TITLE: [Title]
ADDRESS: [Complete Address]
PHONE NUMBER: [Number]
EMAIL: [Email Address]

ENTITY PROVIDING DATA:
NAME OF ENTITY
CONTACT PERSON: [Name]
TITLE: [Title]
ADDRESS: [Complete Address]
PHONE NUMBER: [Number]
EMAIL: [Email Address]

II. PURPOSE, AUTHORITY, AND TERM

A. Purpose

This Agreement facilitates the lawful sharing of data by Name of Entity to the Philippine Cancer Society, Inc., for the purpose of collecting, recording, and maintaining cancer incidence and related health data for the Population-Based Cancer Registry in compliance with the Department of Health's mandate. This data will be used solely for statistical, research, and public health purposes, in line with the principles of transparency, legitimate purpose, and proportionality under the Data Privacy Act of 2012 (Republic Act No. 10173).

B. Legal Authority

This Agreement is executed pursuant to:

1. Republic Act No. 10173 (Data Privacy Act of 2012) and its Implementing Rules and Regulations;
2. Department of Health ("DOH") issuances on the establishment of population-based cancer registries such as Department Circular No 2024-0306 ; and

C. Term

This Agreement shall take effect upon signing by both parties and shall remain valid until [specific date or event, e.g., "completion of the current registry project"], unless earlier terminated under Section X of this Agreement.

III. DESCRIPTION OF DATA

Name of Entity will share the following categories of data with the Philippine Cancer Society:

- **Personal Information:**
  - Name of the Patient
  - Complete Address
  - Birthdate / Age / Sex / Status
  - Hospital Number / Case Number
- **Sensitive Personal Information:**
  - Medical history, diagnosis, tumor site, histology, stage at diagnosis
  - Date Admitted, Date Discharged
  - Date of Treatment (Chemotherapy & Radiotherapy)
  - Laboratory and pathology reports
  - Treatment outcomes

Data will be collected from Medical Records, the Department of Pathology, and the Tumor Registry or Board. No more data than necessary to achieve the stated purpose will be collected.

IV. ACCESS AND TRANSFER OF DATA

A. Method of Access and Transfer

Data shall be transmitted via secure, encrypted digital transfer, password-protected storage devices, or other secure methods agreed upon by the parties.

B. Authorized Personnel

Only personnel duly authorized in writing by the Philippine Cancer Society and Name of Entity, who have undergone data privacy and security training, shall have access to the data.

C. Frequency of Data Sharing

Data will be shared on a [monthly/quarterly/annual] basis, or as otherwise mutually agreed, to maintain up-to-date registry records.

D. Data Protection Officer of the Philippine Cancer Society

The Philippine Cancer Society designates its Data Protection Officer (DPO) as the official responsible for ensuring compliance with Republic Act No. 10173 (Data Privacy Act of 2012), its Implementing Rules and Regulations, and relevant issuances of the National Privacy Commission.

The DPO shall:

1. Monitor compliance with data protection laws and this Agreement;
2. Advise PCS personnel on their data protection obligations;
3. Coordinate with Name of Entity's designated DPO or data privacy focal person;
4. Facilitate communication with the National Privacy Commission and affected data subjects in the event of a data breach; and
5. Maintain a registry of data sharing activities covered by this Agreement.

DPO Contact Information:

Name: [Full Name]
Designation: Data Protection Officer
Address: [Office Address]
Email: [Email Address]
Phone: [Phone Number]

V. SECURITY MEASURES

Both parties shall implement reasonable and appropriate organizational, physical, and technical measures to protect shared data, including but not limited to:

1. Encryption of datasets containing personal and sensitive personal information;
2. Access control mechanisms with user authentication;
3. Secure storage in restricted-access servers; and
4. A data breach management protocol in compliance with the National Privacy Commission's requirements.

VI. CONFIDENTIAL INFORMATION

A. Definition

For purposes of this Agreement, "Confidential Information" shall mean all communications, data, and information—whether commercial, financial, or technical—existing and/or contemplated products and services, schematics, research and development, costs, profit and margin information, finances and financial projections, customers, clients, proprietary ideas, patentable ideas, copyrights, trade secrets, and/or other intellectual property rights, concepts, and ideas in any form, not generally available to the public relating to Name of Entity, its affiliates, or subsidiaries, their past, current or future business, operations, plans, models, or projects, which Name of Entity or any of its directors, officers, employees, agents, consultants, or representatives may disclose or provide access to the Philippine Cancer Society in the course of research, presentations, discussions, or negotiations between them, regardless of whether such information is designated as "Confidential Information" at the time of its disclosure.

B. Form
Confidential Information may be oral, written, electronic, or other machine-readable form; in its original version or as modified, translated, updated, or altered; and may have been originated or obtained by the receiving party.

C. Specific Confidential Dataset
The undersigned shall have access to the dataset variables listed in Section III of this Agreement.

D. Additional Confidential Information
Confidential Information shall also include information disclosed by Name of Entity in writing and marked as confidential, or disclosed orally and later summarized in writing within thirty (30) days.

E. Pre-Agreement Information
Any Confidential Information supplied prior to the execution of this Agreement shall be treated the same as information provided after execution.

F. "As Is" Disclaimer
The Confidential Information is disclosed "as is" without warranties as to completeness, accuracy, merchantability, or fitness for a particular purpose. The receiving party shall hold the providing party free and harmless from claims or liabilities arising from inaccuracies.

G. Data Privacy Compliance
In compliance with RA 10173, the undersigned agrees to maintain the confidentiality of all personal information obtained under this Agreement.

H. Ownership
All Confidential Information and intellectual property obtained remain the sole and exclusive property of Name of Entity.

VII. NON-DISCLOSURE OBLIGATIONS

Throughout the term of this Agreement and after its termination, the Philippine Cancer Society shall:

1. Protect and safeguard all project data and intellectual property;
2. Not disclose data to unauthorized persons;
3. Use data only for the authorized purposes;
4. Not use Confidential Information for any activity in competition with Name of Entity;
5. Ensure secure custody of Confidential Information;
6. Destroy or return Confidential Information upon request or upon termination; and
7. Comply at all times with relevant laws, policies, and regulations on data security, confidentiality, and intellectual property.

VIII. NO RIGHT TO CONFIDENTIAL INFORMATION AND INTELLECTUAL PROPERTY

1. No license is granted to the Philippine Cancer Society to use the Confidential Information or intellectual property except as provided in this Agreement.
2. No claim of ownership over Name of Entity's Confidential Information or intellectual property is conferred.
3. This Agreement does not obligate either party to enter into further agreements beyond the scope herein.

IX. DATA SUBJECTS' RIGHTS

Both parties shall respect the rights of data subjects under the Data Privacy Act.

X. TERMINATION

Either party may terminate this Agreement by thirty (30) days' written notice. Upon termination, all data shall be returned or destroyed, with destruction documented, unless retention is required by law.

XI. GOVERNING LAW

This Agreement shall be governed by the laws of the Republic of the Philippines, including the Data Privacy Act of 2012.

SIGNED:

Philippine Cancer Society, Inc.
By: _____
Name / Title
Date: _____

Name of Entity
By: _____
Name / Title
Date: _____

Annex G: Philippine Cancer Society - Manila Cancer Registry Organization

Board of Trustees

Chairperson: Emily Abrera

Vice-Chairperson & President: Dr. Corazon Ngelangel

Cancer Registry Committee:

Chair: Dr. Angela Crisostomo

Members: Dr. Jaime Galvez-Tan

Dr. Conrado Gabriel Lorenzo III

Dr. Alberto Roxas

Manila Cancer Registry Operations

Registry Director: Dr. Maricar Sabeniano

Registry Manager: Melinda Visoria

Cancer Registrars:
1.Ms. Siony Alcos
2.Raymond Oliveria
3.Charina Rumbao
4.Michael Angelo Domingo
5.Maricar Tentativa
6.Emelyn Cervania
7.Camille Santos
8. Rhea Deang
9. Josephine Isla
10. Saira Agcaoili
11. Mark Masula
12. Ruby Ann De Guzman
13. Anna Lourdes Gutierrez
14. Jessica Dumaquit
15. Loreanne Aranas
16. Dickson Louise Correa
17. Mark Allen Nartatez
18. Kristine S. Manlaguit
19. Rubelyn C. Calayo
20. Maria Lourdes M. Ching