Protocol for Data Request

Introduction

The data from the Puerto Rico Central Cancer Registry (PRCCR) are not publicly accessible, in accordance with its confidentiality policy. However, access to data for research purposes is possible by following the steps of the Protocol for Data Request.

Procedure

Researchers interested in using the PRCCR data for research purposes must:

1. Submit a request to the PRCCR Data Request Evaluation Team (PRCCR-DRET).

   Submitting an application to the PRCCR, can be initiated through the following link: http://rcpr.org/Datos-de-C%C3%A1ncer/Acceso-a-Datos or by sending an email to peticionesrcpr@cccupr.org

2. Fill out a **Level 2** request form.
3. Develop a Letter of Intention (LOI), and follow specific instructions. The LOI must be addressed to the PRCCR-DRET and must include:
   - Title of the proposed research project
   - Objectives
   - Methodology
   - Needed variables
   - Study timeframe

Disclosure

The PRCCR-DRET decides what variables will or will not be released based on scientific merit, data completeness, and whether variables meet the research needs of the proposed research. All Level 2 requests will require an Institutional Review Board (IRB) approval, and the PRCCR-DRET approval (support letter) must be obtained before submission for IRB approval.

It is important to highlight that the PRCCR Law No. 113, under Article 8 (*Disclosure of information for scientific and research purposes*), the first section states:

"…the Registry is hereby authorized to provide the minimum data to researchers and scientists that are necessary to answer the research question while preserving the confidentiality of both the patient and the reporting entities pursuant to the appropriate federal and Commonwealth laws."

Approval for Level 2 requests by PRCCR-DRET can take from 2 to 12 months, depending on the complexity of the request. Please, plan accordingly.

Fees and collaborations

Some types of requests, depending on the specifications, may generate a fee and/ or require a formal collaboration with the PRCCR (authorship). This may include:

- Research requiring PRCCR regular non-confidential data items (Appendix A).
- Research requiring review of records (quality control).
- Research requiring claims information (insurance type, comorbidities, treatment, etc.)
- Research requiring PRCCR personnel to perform some analyses.
- Research requiring any programming process.
- Research requiring data coordination.
- Research requiring linking PRCCR data to an external database. (Please note that all linkages must occur at the PRCCR. No offsite linkages are allowed.)

Appendix A: PRCCR non-confidential data items

Patient Demographic Data

- Sex
- Age at Diagnosis
- County/Health Region at Diagnosis

Case Specific Information

- Primary Site
- Date of Diagnosis
- Histology
- Behavior
- Tumor Grade
- Laterality
- Diagnostic Confirmation
- Tumor Size
- Regional Nodes Examined
- Regional Nodes Positive
- Summary Stage (Localized, Regional, Distant, or Unstaged) *

Other Primaries

- Case Sequence Number

First Course of Treatment *

- Surgery (yes or no)
- Chemotherapy (yes or no)
- Radiotherapy (yes or no)
- Hormone (yes or no)
- Date of treatment

Follow Up Information

- Date of Last Contact
- Vital Status
- Cause of Death

DISCLAIMER

*** Stage at Diagnosis / First Course of Treatment** – Sensitivity and completeness of these variables may vary by cancer site and patient characteristics. For missing/unknown information we do not know whether stage was not determined or treatment was not received by the patient or whether this information was not captured by the PRCCR.