

## Pharmaceutical Research Computing Health Services Research Support Data (HSRSD) Policy

**Approved by the PRC Advisory Committee:** August 2018

**Implementation Date:** August 2018

**Modification Date:**

### **Background:**

Annually, Pharmaceutical Research Computing maintains restricted licensed agreements for several software licenses. These licenses provide PRC team members use and access to files provided under licensed agreements. PRC maintains the licenses and derived data products on behalf of the clients who require access to these data products. Data resources include the following:

- Centers for Medicare and Medicaid: International Classification of Diseases 9 and 10 (ICD-9 & ICD-10) Codes
  - **Purpose:** A standardized system to classify mortality and morbidity statistics. Found as standardized documentation in the patient's electronic health record for diagnostic, billing (claims reimbursement) & reporting purposes (clinical research).
  - Developed by the World Health Organization (WHO) with changes and modifications monitored by the National Center for Health Statistics (NCHS- part of CMS) within the US.
  - Includes two coding systems with a third awaiting final endorsement for use (ICD-11)
    - ICD-9 / ICD-9-CM (Clinical Modification) US version
    - ICD-10 / ICD-10-CM US version
- First Databank: National Drug Codes (NDC)
  - **Purpose:** Unique product identifier for drugs registered with the FDA. 10-digit NDC codes are assigned and appear on each human prescription/non-prescription medication. 11\_digit codes are required for billing purposes and includes the insertion of a 'leading zero' into the appropriate section of the number.
  - Developed by the Federal Drug Administration (FDA) for all registered drugs beginning in 19072 under the Drug Listing Act.
- Optum Ingenix: Healthcare Common Procedure Codes (HCPC)
  - **Purpose:** Reports supplies, equipment, procedures and devices as well as serves as a supplement when procedures are not captured using CPT coding.
  - Developed by the Centers for Medicare and Medicaid Services (CMS) with the exception of the dental codes. Dental codes (D-codes) are developed and maintained by the American Dental Association (ADA).
  - Includes two (2) levels:
    - HCPCS Level I: CPT coding system
    - HCPCS Level II: Supplies, products, and services not included in CPT
- Optum Ingenix: Current Procedural Terminology (CPT) Codes
  - **Purpose:** Standard for documenting medical services and procedures. Helps determine the amount of reimbursement a provider will receive.
  - Developed by the American Medical Association (AMA)
  - Includes three (3) categories
    - Category I: Reporting claims and getting paid
    - Category II: Measures performance
    - Category III: Codes that allow for monitoring of new and developing technology and services

PRC personnel have years of experience in working with these datasets and in understanding the available attributes needed to conduct analysis (e.g. what information can be ascertained from the different data sets,

what data files affiliated with claims based data would need to be included for productive data extractions, etc.)

The purpose of this document is to specify how PRC is to administer the use of the restricted licensed data and PRC-prepared analytic files.

PRC's licensed agreements outline the following:

- First Databank sublicenses various copyrighted databases and medical, pharmaceutical and nutritional information and periodic updates thereto ("Databases"), related access software products (Toolkits") and user manuals ("Manuals") referred to collectively, as the Knowledge Bases".
- Licensee (i.e., PRC) shall have no right to use, modify, reproduce or distribute the Licensed Products, nor the rights to license third parties to exercise any rights with regard to the Licensed Products.
- Licensee shall not copy, reproduce, store in a retrieval system, sublicense, convey, transfer, redistribute, grant other rights in, or permit any unauthorized use of the Licensed Products, or any of them, in any form or by any media (electronic, mechanical, photocopy, recording, or otherwise), on either a permanent or temporary basis to any third party.
- Licensee shall use the Licensed Products solely in a single computer system at the approved site.
- Licensee has no implied licensed rights to the licensed products made available through FDB & Optum Ingenix. In the event that these restricted licenses are not renewed, all licensed products or other created documents must be removed/purged from the licensee's system and attestation statements sent within 30 days of termination.

### ***Policy and Affiliated Fee Structure:***

The policy and fees associated with the use of these resources include:

- I. Type of HSRSD Purchase
  1. Annual Cost
    - a. Project PI confirms the start of the 12-month period whereupon the resource can be accessed as needed without additional fees
    - b. Client billing will be on the first invoice in project start up or when resource(s) are identified as being needed
  2. Per-Project Simple Vs. Complex Algorithm
    - a. Utilization is for one project
    - b. Client billing will be on the first invoice in project start up or when resource(s) are identified as being needed
    - c. Use of the Simple or Complex Algorithm will be based on the following:
      - SIMPLE ALGORITHM:
        - Cost will include an amount to cover the HSRSD and PRC time
        - 1-3 Codes provided by PI to be researched within one of the available HSRSD databases with an output of 1-2 fields/variables (e.g. 1-3 NDC codes provided, returned generic & brand drug names)
        - No computation needed, includes data extraction only
      - COMPLEX ALGORITHM
        - Complex coding needed to create an output (e.g. requires more than a simple data extraction)
        - More than 2 fields/variables output needed by PI
        - More than one HSRSD database needed for research by PI

## II. Client Type Description

1. PHSR Client Contract
  - a. Available to PHSR investigators
  - b. PHSR graduate program
  - c. PHSR Fellows
2. UM Contract
  - a. Available only to a UM affiliate
3. External Client Contract
  - a. Available to clients external to UM
  - b. Utilization is for individual contract
  - c. Contract execution date determines the 12-month period

PRC will categorize project request as a simple or complex algorithm based on the details shared by the inquiring client.

To allow all potential users time to determine their need of FDB, PRC will extend the option of allowing UM clients to explore the value of the Annual Buy-in. If a client is unsure if they will need a full Annual Buy-in, PRC will monitor individual PI Per-Project access fees and will coordinate to take the least amount annually, potentially rolling the PI in the Annual Buy-in.

Example:

### Simple Algorithm

PRC's client has shared two (2) NDC codes for which they are interested in learning all generic and brand names associated with the provided codes.

Annual Buy-In Fees		
Client Type	Annual Cost	
PHSR Client Contract	\$4,000	
UM Client Contract	\$5,000	
External Client Contract	\$7,500	
Per-Project Fees		
Client Type	Simple Algorithm	Complex Algorithm
PHSR Client Contract	\$500 + PRC hourly rate	\$2,000
UM Client Contract	\$2,500	\$5,000
External Client Contract	\$4,000	\$8,000

### Complex Algorithm

PRC's client would like to build a crosswalk file using ICD-9 codes and creating a list of ICD-10 codes.