# Extract Background and Status

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| --- | --- |
| **JIRA:** | CCDA-3913 |
| **Study PI:** | Jenni Sheng |
| **Study Title:** | Cardiometabolic Screening Program in Breast Cancer Patients |
| **Contact:** |  |
| **Date and Version:** | May 13, 2022 Version 2 |
| **Extract purpose:** | Determine eligibility for study recruitment |
| **Current IRB status:** | IRB00285627 - IRB-X, Approved |
| **IO/Cost Center:** | 80054485 |
| **Extract frequency:** | one-time |
| **Data Source:** | Epic Clarity |
| **Extract Structure:** | pipe-delimited flat files |
| **Risk Tier (Low, Medium, High):** | High - Destination=SAFE, Sensitive Data = Yes, number of patient records <500, data type to study team= PHI, data type to share = None. |
| **Will data be shared outside the covered entity?** | No |
| **Work Estimate** | **[TBD]**  CCDA rate is $118/hour  **By selecting this check box, the study PI agrees to pay the CCDA in full for actual hours worked, not including the 2 hours subsidized by the ICTR.** |

# Inclusion criteria

Only patients with the following criteria will be included in the extract results:

* Adults (>= 18 years of age)
* Having an upcoming appointment at one of the following locations with one of the listed providers for the following timeframe July 2022- Dec 2022:
  + 110107517    JHH VRGH BREAST GYNONC: Melissa Camp, Amy Deery, David Euhus, Lisa Jacobs, Danjela Jelovac, Julie Lange, Angelina Johnson, Justin Mahosky, Anisha Ninan, Patricia Njoku, Katherine Papthakis, Carol Riley, Cesar Santa-maria, Vered Stearns, Jessica Tao, Antonio Wolff
  + 113000510    GSS SOM ONCOLOGY: Rima Couzi, John Fetting, Danjela Jelovac, Antonio Wolff, Nelli Zafman
  + 110400323 SMH MEDICAL ONCOLOGY: Karen Smith, Mary Wilkinson, Cesar Santa Maria, Raquel Nunes

# Exclusion criteria

Patients known to be deceased in Epic

Patients with the following Metastatic ICD10 listed anytime on their Problem List

* C78 Secondary malignant neoplasm of respiratory and digestive organs
* C78.0 Secondary malignant neoplasm of lung
* C78.1 Secondary malignant neoplasm of mediastinum
* C78.2 Secondary malignant neoplasm of pleura Malignant pleural effusion NOS
* C78.3 Secondary malignant neoplasm of other and unspecified respiratory organs
* C78.4 Secondary malignant neoplasm of small intestine
* C78.5 Secondary malignant neoplasm of large intestine and rectum
* C78.6 Secondary malignant neoplasm of retroperitoneum and peritoneum Malignant ascites NOS

##### C78.7 Secondary malignant neoplasm of liver and intrahepatic bile duct

##### C78.8 Secondary malignant neoplasm of other and unspecified digestive organs

#### C79 Secondary malignant neoplasm of other and unspecified sites

##### C79.0 Secondary malignant neoplasm of kidney and renal pelvis

##### C79.1 Secondary malignant neoplasm of bladder and other and unspecified urinary organs

##### C79.2 Secondary malignant neoplasm of skin

##### C79.3 Secondary malignant neoplasm of brain and cerebral meninges

##### C79.4 Secondary malignant neoplasm of other and unspecified parts of nervous system

##### C79.5 Secondary malignant neoplasm of bone and bone marrow

##### C79.6 Secondary malignant neoplasm of ovary

##### C79.7 Secondary malignant neoplasm of adrenal gland

##### C79.8 Secondary malignant neoplasm of other specified sites

##### C79.9 Secondary malignant neoplasm, unspecified site

##### C50.919 Malignant neoplasm of unspecified site of unspecified female breast

# Extract Sections and Format

The CCDA will deliver pipe-delimited flat files to the approved destination [SAFE desktop]. Each file is organized by clinical content type (patient demographics, encounters, medications, lab results, etc.) and can be linked by a common identifier (patient ID, encounter ID, etc.).

**The data delivery represents a PHI dataset.**

**The study protocol has been approved for** [**sensitive data**](https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/research_using_pmap.html)**.**

**The study team acknowledges the data format and its contents.**

## Demographics

|  |  |
| --- | --- |
| **Data Element** | **Notes** |
| Enterprise ID |  |
| MRN | Other facility MRN (JH, BV, etc.) |
| Age |  |
| Gender |  |
| Race |  |
| Ethnicity |  |
| Patient Address Info | Address lines 1 and 2, city, state, zip |
| Patient email |  |
| Last recorded BMI |  |
| Date of last recorded BMI |  |

## Encounters

See inclusion criteria: provide encounter data for upcoming appointments for providers and departments/clinics listed.

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| --- | --- |
| **Data Element** | **Notes** |
| Enterprise ID |  |
| Encounter ID | CSN |
| Encounter Department/location |  |
| Visit Provider |  |
|  |  |

## Lab Results

Hba1c & Lipid panel

Interested in most recent value.

|  |  |
| --- | --- |
| **Data Element** | **Notes** |
| Enterprise ID |  |
| Encounter ID |  |
| Result date/time |  |
| Collection date/time |  |
| Order date/time |  |
| Lab name | HbA1c and Lipid panel |
| Base name | The CCDA will provide a list of lab components for the study team to verify |
| Value – numeric |  |
| Value – text |  |
| Text comments |  |
| Units |  |
| Reference range – low |  |
| Reference range – high |  |
| Ordering department or provider |  |

# Comments

1. The CCDA will conduct a review of the IRB protocol to ensure that requested data match what was approved by the IRB.
2. Data is provided in alignment with your IRB approval. Data provided may not be used to secure additional data for purposes not approved for your study.