PCaP Datasets – Definition/Algorithm (2010)

Dataset #1: Balanced by Race, State, and Aggressiveness
Previously - Phase I dataset
N=200 subjects

- Includes post-Katrina, LA and NC subjects only
- 50 subjects in each state-race category comprised of 25 high and 25 low aggressive prostate cancer subjects
- Diagnosis date after 07/01/2004
- PCaP in-home visit completed
- Blood collected during PCaP in-home visit
- 8 or more Red Top serum aliquots
- 6 or more Yellow Top (EDTA) plasma aliquots
- 1 urine tube with preservative (crystalline ascorbic acid) and 1 tube without preservative
- 3 or more 100ul iDNA (DNA extracted from immortalized cell lines) aliquots with 100ng/ul
- Aggressiveness classification not missing
- Subject consented to other research use of samples including prostate cancer research
  (Note: this entire set can be used for any type of research)
- Not missing prostate-specific antigen (PSA)
- Not missing Gleason sum (Gleason sum or Gleason score = Primary Gleason Grade (grade 1-5 assigned to most common tumor pattern) + Secondary Gleason Grade (grade 1-5 assigned to second most common tumor pattern)
- Not missing clinical stage

Dataset #2: Radical Prostatectomy (RP)
Previously - Phase II dataset
N=200 subjects

- Includes NC subjects only
- 100 AA and 100 CA
- Subjects must have radical prostatectomy tissue on PCaP tissue microarrays # 1-5
- Diagnosis date after 07/01/2004
- PCaP in-home visit completed
- Blood collected during PCaP in-home visit
- 8 or more Red Top serum aliquots
- 6 or more Yellow Top (EDTA) plasma aliquots
- 1 urine tube with preservative (crystalline ascorbic acid) and 1 tube without preservative
- Aggressiveness classification not missing
- Subject consented to other research or prostate cancer only future sample use
  (Note: this entire set can be used for prostate cancer research only – even though some subjects in this set may have consented to future use for other research)
- Not missing prostate-specific antigen (PSA)
- Not missing Gleason sum (Gleason sum or Gleason score = Primary Gleason Grade (grade 1-5 assigned to most common tumor pattern) + Secondary Gleason Grade (grad 1-5 assigned to second most common tumor pattern)
- Not missing clinical stage

Dataset #3: Untreated (self-report)
Previously - Phase III dataset
N=251 subjects

- Includes pre-K, post-K, LA and NC subjects
- All subjects must be underlined untreated based on the self-reported questionnaire variable, i.e. untxdQx = 1 (UnTxd prior to the PCaP visit)
- Diagnosis date after 07/01/2004
- PCaP in-home visit completed
- Blood collected during PCaP in-home visit
- 8 or more Red Top serum aliquots
- 6 or more Yellow Top (EDTA) plasma aliquots
- 1 urine tube with preservative (crystalline ascorbic acid) and 1 tube without preservative
- 3 or more 100ul iDNA (DNA extracted from immortalized cell lines) aliquots with 100ng/ul
- Aggressiveness classification not missing
- Consented to other or CaP only future sample use
  (Note: this entire set can be used for prostate cancer research only – even though some subjects in this set may have consented to future use for other research)
- Not missing prostate-specific antigen (PSA)
- Not missing Gleason sum (Gleason sum or Gleason score = Primary Gleason Grade (grade 1-5 assigned to most common tumor pattern) + Secondary Gleason Grade (grad 1-5 assigned to second most common tumor pattern)
- Not missing clinical stage

Dataset #4: Feasibility
Previously - Phase IV dataset
N=200 subjects

- Includes post-K, LA and NC subjects only
- Should not overlap at all with Phase I, II or III
- Should be a random selection of PCaP subjects (will likely create the 50:30:20 distribution of low to high CaP aggressiveness given the random selection)
- Diagnosis date after 07/01/2004
- PCaP in-home visit completed
- Blood collected during PCaP in-home visit
- 8 or more Red Top serum aliquots
- 6 or more Yellow Top (EDTA) plasma aliquots
- 1 urine tube with preservative (crystalline ascorbic acid) and 1 tube without preservative
- 3 or more 100ul iDNA (DNA extracted from immortalized cell lines) aliquots with 100ng/ul
- Aggressiveness classification not missing
- Consented to other research use of samples including CaP
  (Note: this entire set can be used for any type of research)
- Not missing prostate-specific antigen (PSA)
- Not missing Gleason sum (Gleason sum or Gleason score = Primary Gleason Grade (grade 1-5 assigned to most common tumor pattern) + Secondary Gleason Grade (grad 1-5 assigned to second most common tumor pattern)
- Not missing clinical stage

NOTE: For any serum request, accompanying data should include the variable regarding transport conditions (ambient or on ice) relevant only to UNC serum samples collected after 4/30/2007 (N=835 subjects).