The PROSPR Initiative:

Competitive Revision for the Collection of Cervical Cancer Screening Process Data by Two Existing PROSPR Research Centers

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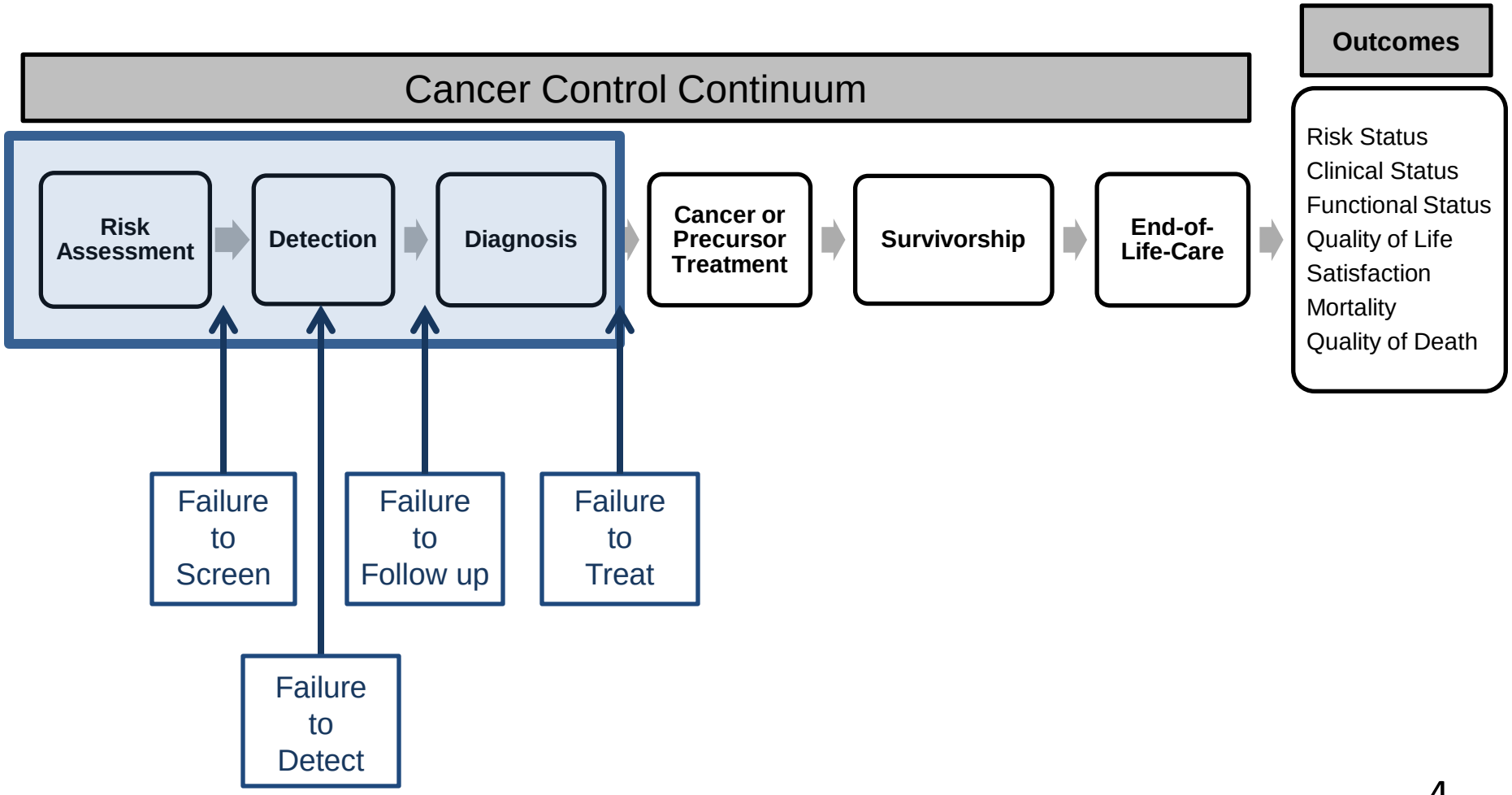
Etiology and Prevention of Cervical Cancer

- Infection with high-risk types of human papilloma virus (HPV) causes virtually all cervical cancers
  - ~70% due to HPV16 and HPV18
- Diagnosis and treatment of precursor lesions (CIN2 and CIN3) can prevent incident cervical cancer
- Since introduction of cervical cytology (Pap) in the U. S., cervical cancer has decreased by 80%
  - Issues of overuse and underuse
- New technologies (HPV testing and vaccination) are changing the landscape of cervical cancer prevention

The Landscape of Cervical Cancer Prevention is Changing Rapidly

- 2012 release of new guidelines/recommendations
  - Longer screening intervals, HPV co-testing, age considerations
  - Are patients and providers accepting of new guidelines?
- Girls vaccinated as adolescents will soon be reaching screening-appropriate ages
  - Will screening strategies need to change further?
- Possibility of specimen self-collection

Rationale for PROSPR: Breakdowns Can Occur at Multiple Points in the Cancer Screening Process



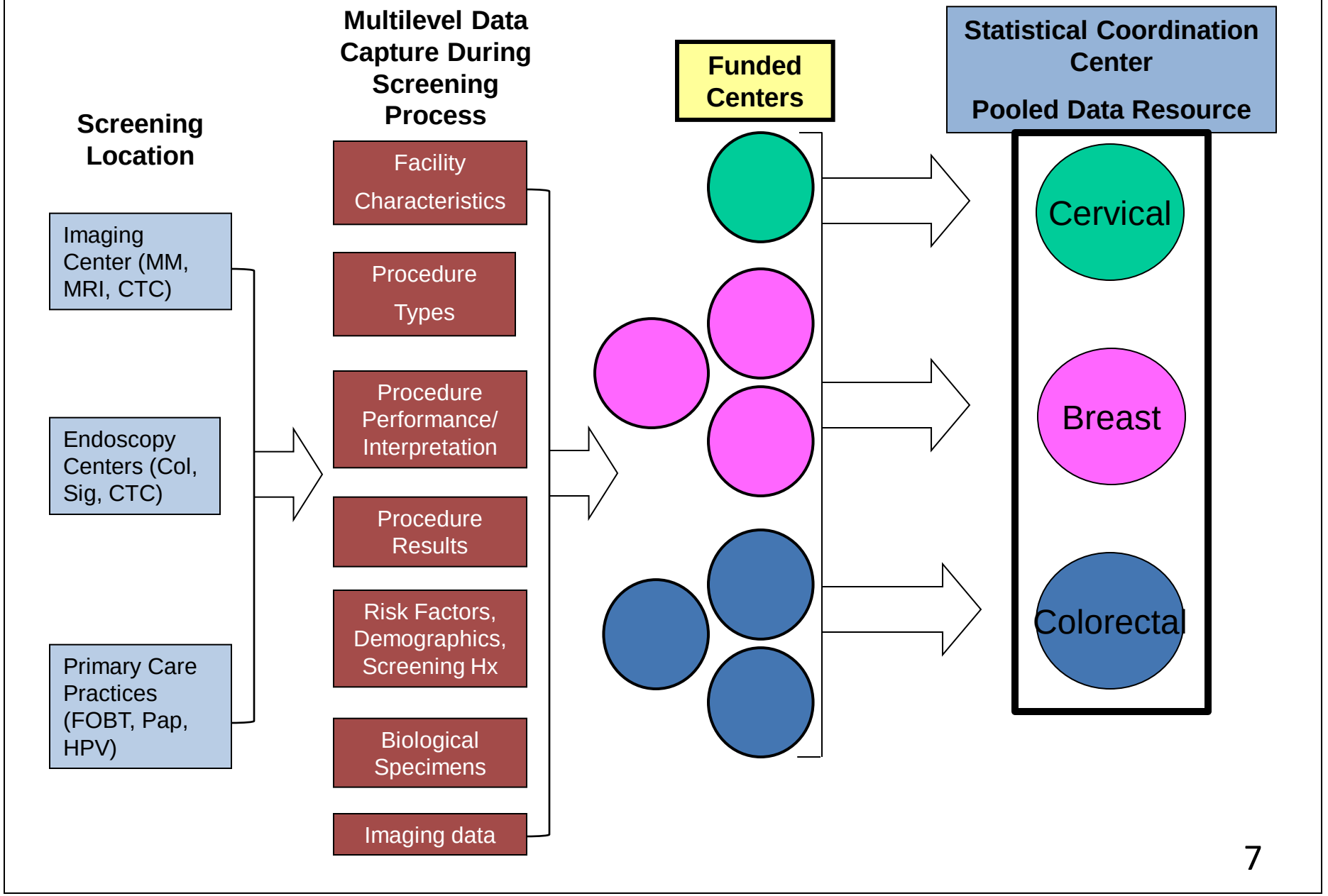
PROSPR's Objective

- **Promote coordinated, multidisciplinary, and multi-level research to evaluate and improve the cervical, breast, and colorectal cancer screening processes in clinical practice through:**
  - Collection of multi-level data
    - Patient, provider, facility, and health care system factors
  - Identification of screening process failures and potential remedies
  - Evolution of screening strategies beyond age-based to more encompassing risk-based strategies

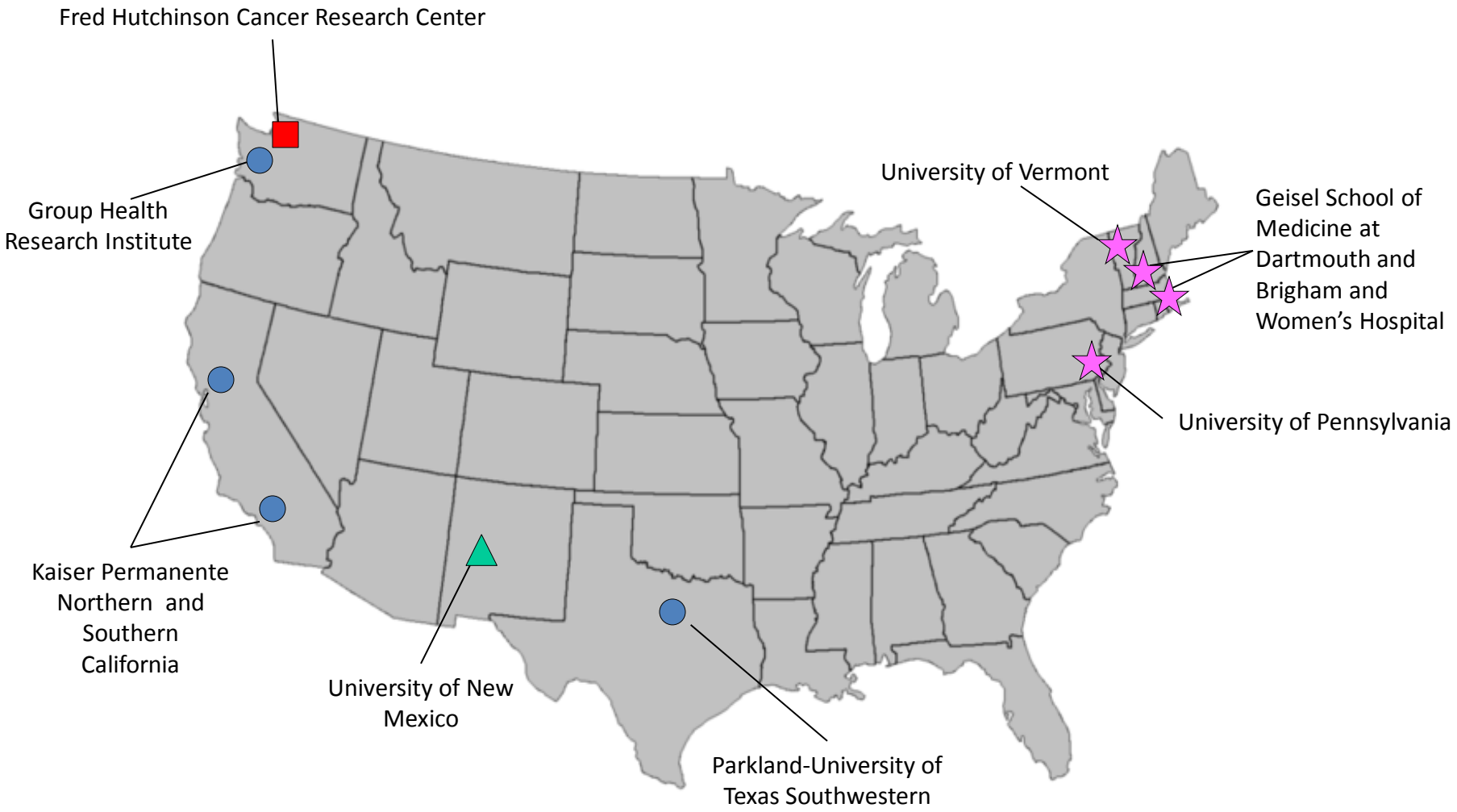
Research Center Activities

- **Submit core screening process data to the central data repository housed at the statistical coordinating center**
- **Conduct multicenter, collaborative projects**
- **Conduct three individual research projects**
  - Project 1: Comparative effectiveness research (CER) project
    - Measure the benefits and harms of screening processes across risk profiles
    - Examine comparative effectiveness of the screening process for different tests
  - Projects 2 and 3: At the discretion of the applicant
  - Projects linked by an applicant-proposed research theme

PROSPR Research Data Infrastructure



Funded PROSPR Research Centers



Need for Multiple Research Centers Within Each Organ Site

- Challenges to the successful completion of the screening process may differ in different
  - High-risk populations
  - Healthcare systems
- A thorough understanding of the process requires comparisons across multiple settings
- Ultimately, the goal is to
  - Develop general approaches for improving the process, AND
  - Tailor them for application in different environments

Composition of Existing PROSPR Research Centers

PROSPR Research Center	High-Risk Groups Included	System
University of New Mexico (Cervical)*	Hispanic Native American Low-income rural	State-wide registry
Group Health Cooperative (Colorectal)	Asian American Medicaid	Integrated health care delivery system
Parkland-UT Southwestern (Colorectal)	African American Hispanic Low-income urban Under- or uninsured	Safety-net clinical provider network
Kaiser Permanente Northern and Southern California (Colorectal)	African American Hispanic Asian American	Integrated health care delivery system
University of Pennsylvania (Breast)	African American Low-income urban	Integrated health care delivery system
Dartmouth Institute and Brigham and Women's Hospital (Breast)	African American Hispanic Medicaid Low-income urban	Primary care clinical networks
University of Vermont (Breast)	Rural	State-wide registry

*Only 1 cervical research center application scored in the fundable range

PROSPR Can Be Leveraged to Address Important Cervical Cancer Screening Questions

- **Short-Term**
  - Does co-testing with HPV and Pap occur more frequently in integrated health care systems than in small private practices? Does use of co-testing differ by provider specialty?
  - Despite their lower risk of HPV infection, are vaccinated women more likely to be screened for cervical cancer due to increased likelihood of contact with their health care providers?

PROSPR Can Be Leveraged to Address Important Cervical Cancer Screening Questions

- **Long-Term**
  - At what intervals are women being screened by Pap only? By co-testing? Are patient-, provider-, or system-level factors the strongest predictors of adherence to recommended screening intervals?
  - Given that racial and ethnic minority women, and particularly recent immigrant populations, are at the highest risk of cervical cancer, what are the most effective and culturally sensitive strategies for improving attendance at screening and follow-up of abnormal screening exams?

Competitive Revisions to Two Existing PROSPR Research Centers

- Capture cervical cancer screening data during a time of rapid change in screening practice
- Effort will focus on
  - Submission of core screening process data to the central data repository housed at the statistical coordinating center
  - Conduct of multicenter, collaborative projects
- Increase PROSPR's research contributions with relatively modest additional resources compared to the cost required to set up these systems de novo

Advantages of and Justification for Competitive Revisions

- Takes advantage of existing infrastructure, to allow for rapid onset of data collection
- Unique capacity of existing centers
  - Several PROSPR Research Centers are ready to collect (or in the past have collected) cervical cancer screening data
  - No other NIH grants are collecting multilevel data to evaluate the entire screening process
  - CDC surveillance efforts do not capture these types of data
- Would align with final 2 years of parent grants
- Would allow for comparison of the screening process for 2 cancers within the same population

Budget for PROSPR Cervical Enhancement

- **Competitive revision to PROSPR Research Centers**
  - Total cost based on median annual budget for data collection core within funded PROSPR Research Centers
    - $650K per center per year
  - Total cost for the addition of the 2 cervical centers
    - First year: $1.3M
    - All years (2): $2.6M
- **Administrative supplement to the Statistical Coordinating Center**
  - Total cost
    - $35K per additional cervical center per year
    - $140K for 2 centers over 2 years

Conclusion

- Goal is to capture cervical cancer screening process data during this time of rapid change
- Address key research questions in high-risk populations and different healthcare systems
- Competitive revisions to the existing PROSPR Research Centers represent the most efficient way to accomplish this goal

PROSPR

Population-based Research Optimizing Screening through Personalized Regimens

Working together to improve cancer screening in communities