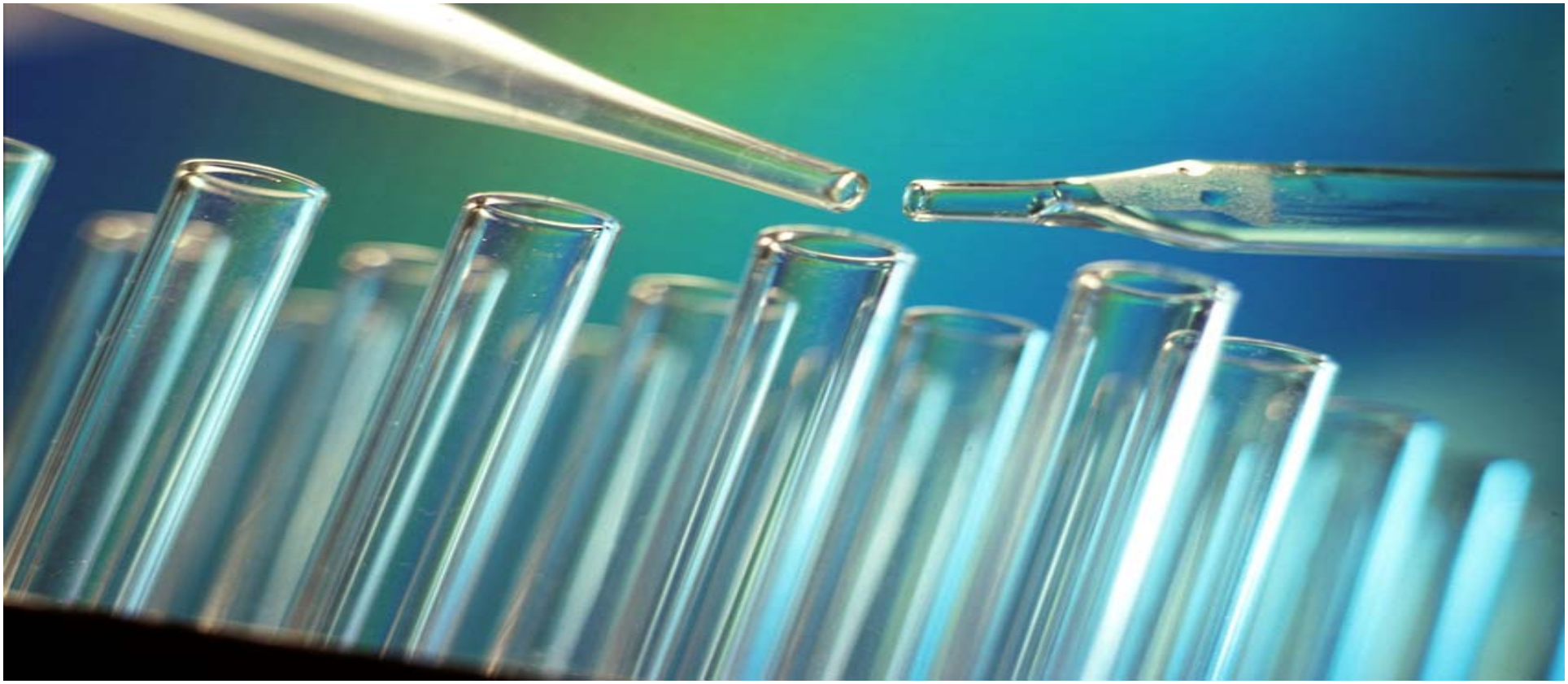

The KP Research Bank

Karen Emmons
VP for Research
Acting Executive Director, KP Research Bank

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Our Vision

- One of the world's largest and most diverse repositories of genetic, environmental, and health data
- A shared, research-ready resource
- Coordinated effort with standardized recruitment and central processing and storage
- All 7 KP regions represented in development and maintenance

Why did KP invest in the Research Bank?

- To create a world class resource -- a community benefit
- To play a critical role in pursuit of transforming healthcare by improving our understanding of the genetic and environmental factors involved in complex diseases
- To create a platform for translation of genomics into care delivery

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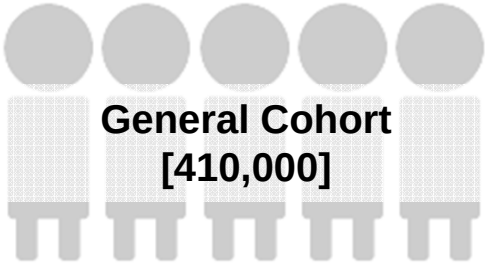
The KP Research Bank Will Have Samples From 500K Members



General Cohort [410,000]

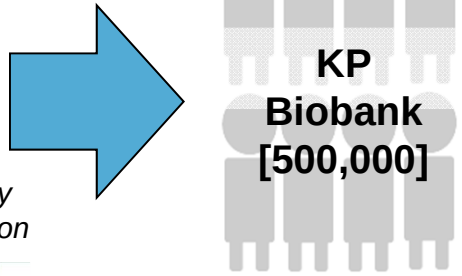
Enables research of relevance to all KP members across a broad spectrum of common diseases and builds on existing 200,000 samples

Pregnancy Cohort [60,000]

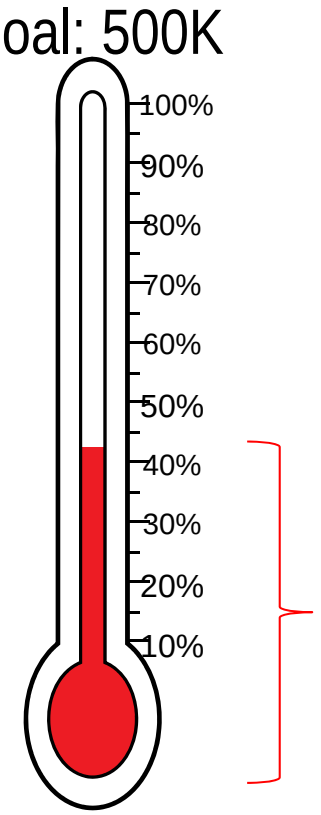
Will be among the largest and richest pregnancy research cohorts in the world. This cohort builds on an existing 20,000 samples

Cancer Cohort [30,000]

Linked to tissue banks; Oncology is an early adopter of genomic medicine; over half of KP researchers focus on cancer



KP Biobank [500,000]



220,000 samples have already been collected via 4 regional Biobanks

Enrolled & Sampled

- Future studies will propose use of our samples to create genomic data & data we create
- Future studies will collect additional data/samples

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KP BB Foundations and Acknowledgements

Development of **the KPNorthwest (NW) Biobank** was made possible with support from the Oregon Clinical and Translational Research Institute (OCTRI), grant number UL1 RR024140 from the National Center for Research Resources (NCRR), a component of the National Institutes of Health (NIH), NIH Roadmap for Medical Research; the MJ Murdock Charitable Trust, and institutional support from the Center for Health Research (CHR), and Kaiser Permanente (KP) NW.

Development of the **KP Southern California Biobank** program was made possible with support from the Program Office Community Benefit Program and Southern California Permanente Medical Group.

Development of the **KP Georgia Biobanking Program** was made possible with support from the Kaiser Permanente of Georgia Community Benefit grants program.

The Research Program on Genes, Environment, and Health (RPGEH), which serves as a major foundation for the KP Biobank, was developed beginning in 2005 at the KP Division of Research in Northern California by Catherine Schaefer (Director), Neil Risch (Co-Director), Lisa Croen, Eric Jorgenson, Lawrence Kushi, Charles Quesenberry, Sarah Rowell, Carol Somkin, Stephen Van den Eeden, Larry Walter, and Rachel Whitmer. The aims of the RPGEH were: 1) to develop a research resource that combined data from biospecimens (serum, DNA), electronic health records, self-report surveys, and environmental databases from broadly consented adult members of KP Northern California, and 2) to conduct research on genetic and environmental influences on health and disease to improve health and medical care. The RPGEH resource at the end of 2013 included: (1) demographic and behavioral surveys from 430,000 participants; (2) biospecimens (DNA, buffy coat, serum, and and/or saliva) from 204,816 participants, including 13,414 pregnant women; (3) genome-wide genotype data (70 billion SNP genotypes) on 110,266 participants, referred to as the Genetic Epidemiology Research on Adult Health and Aging (GERA) cohort. Funding of the RPGEH was provided to C. Schaefer (PI) and N. Risch (co-PI) by the Wayne and Gladys Valley Foundation, The Ellison Medical Foundation, the Robert Wood Johnson Foundation, Kaiser Permanente Northern California , and the Kaiser Permanente National and Regional Community Benefit Programs. The GERA cohort was funded by a grant from NIH to RPGEH & UCSF (RC2 AG036607; C. Schaefer and N. Risch, PIs). The KP Biobank access process is currently being established; RPGEH currently provides access to internal and external researchers via an application and review process, and access to the GERA genotype data and selected phenotypes on 78,466 individuals is available through dbGaP (Study Accession: phs000674).

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Research Biobanks are Critical to Care Transformation

Optimal Research Biobank → **Research Opportunities Area** → **Future of Care**

Three Biobank Success Factors

Large Sample Size

Analytical power for population subsets and rare conditions

Mastering EMR Data

Tie to clinical history and assess longitudinal clinical impact

Participant Diversity

Breadth of research inquiry and applicability

Research Opportunities Area

- Gene-Disease Association
- Environmental Impacts
- Molecular Diagnostics
- Pharmacogenomics
- Epigenetics
- Metabolomics
- Proteomics
- Intervention Response

Future of Care

Biobank-enabled research will improve our understanding of the genetic and environmental factors involved in complex diseases

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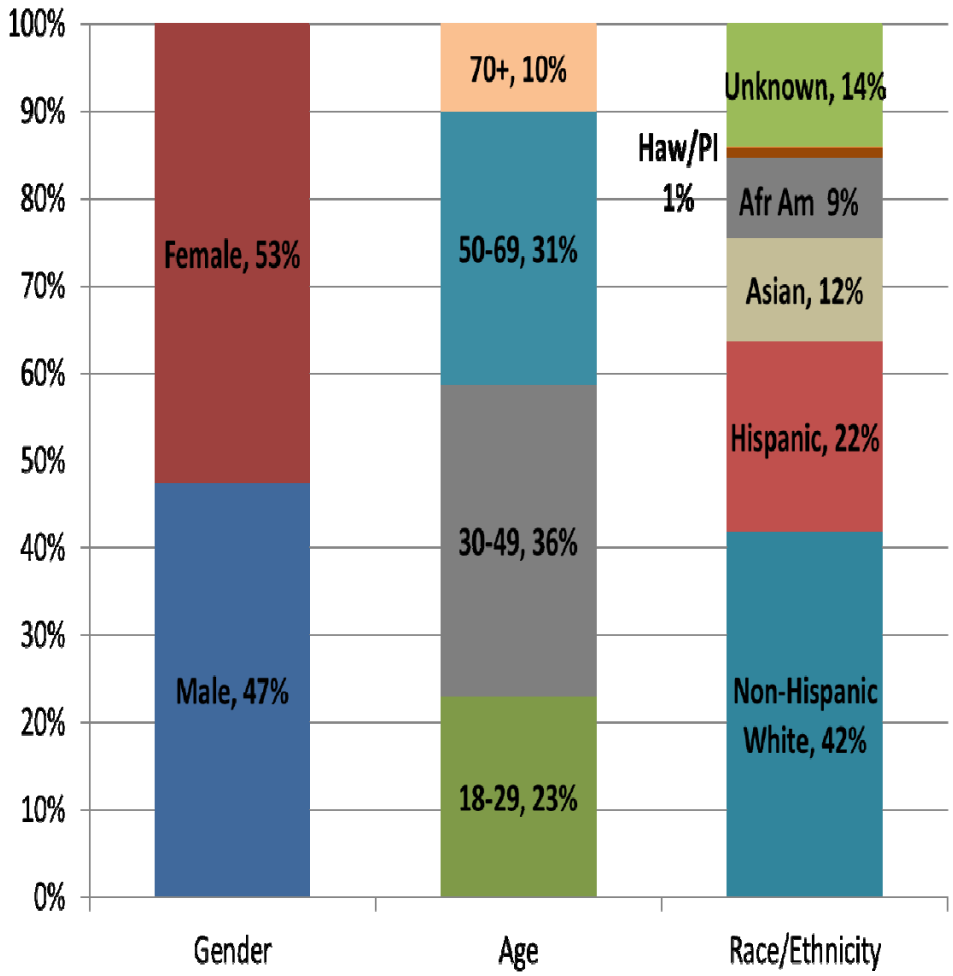
KP Members: A Diverse Population

- KP now has over 10 million members across 7 regions
- KP's membership is unusually diverse among major health care delivery systems with research programs
  - Over 50% of KP members are minority race-ethnicity, with each of the major race-ethnicity groups well represented
  - Representation of lower income members is increasing



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KP Research Bank Context

We're complex! This is the first ever program-wide effort of this scale.

- 7 KP regions (and research centers) + Program Office; Health Plan/Hospital & Permanente Medical Groups
- Inter-regional research coordination via National Research Council
- Need agreement/ consensus from many different stakeholders across regions
- Sharing data, including PHI, across regions
- Differences in regional systems & labs
- 8 IRBs with different adaptations of national standards
- 220K samples already collected; robust research activities underway

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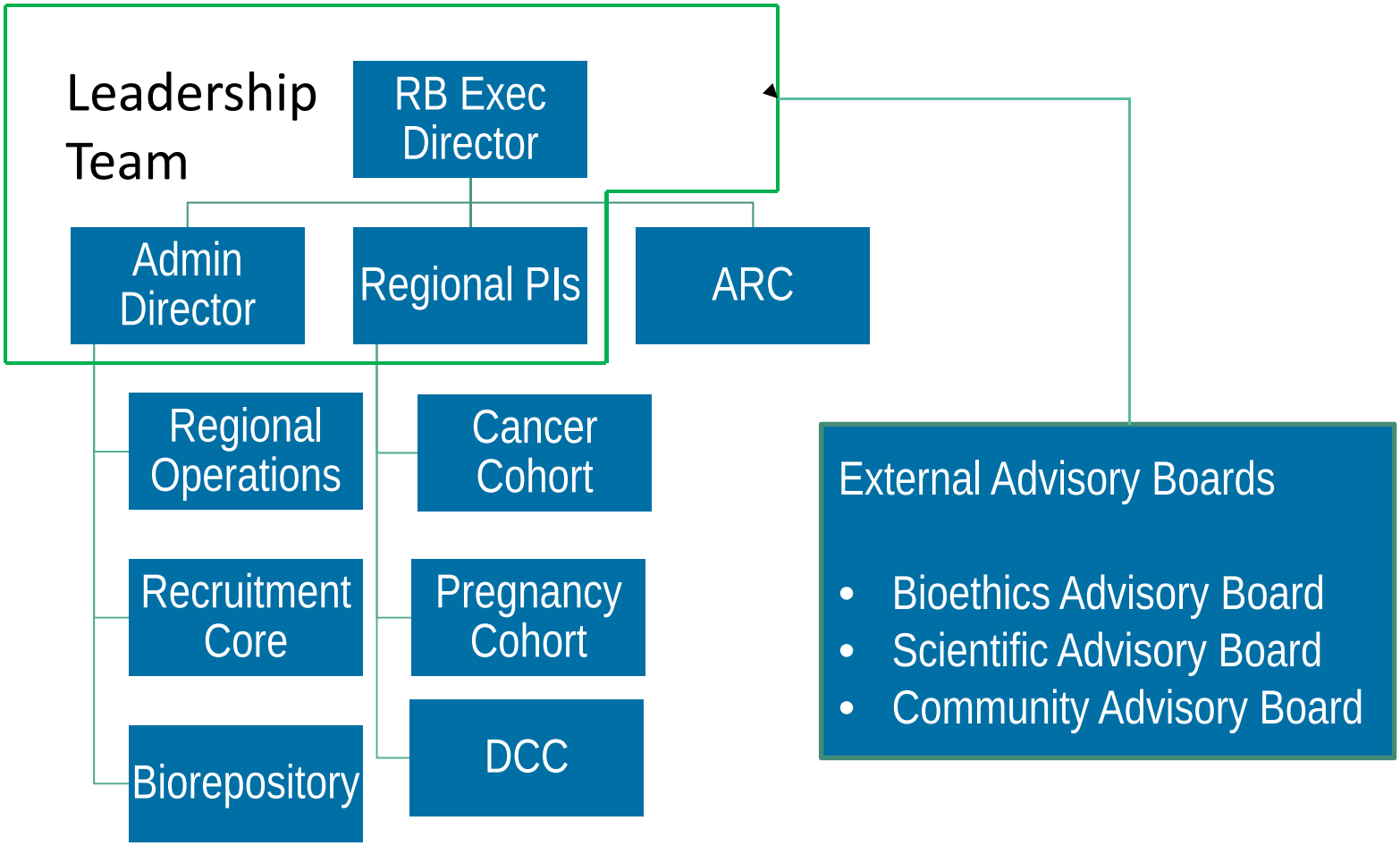
KP Research Bank Organizational Chart: Functional Structure



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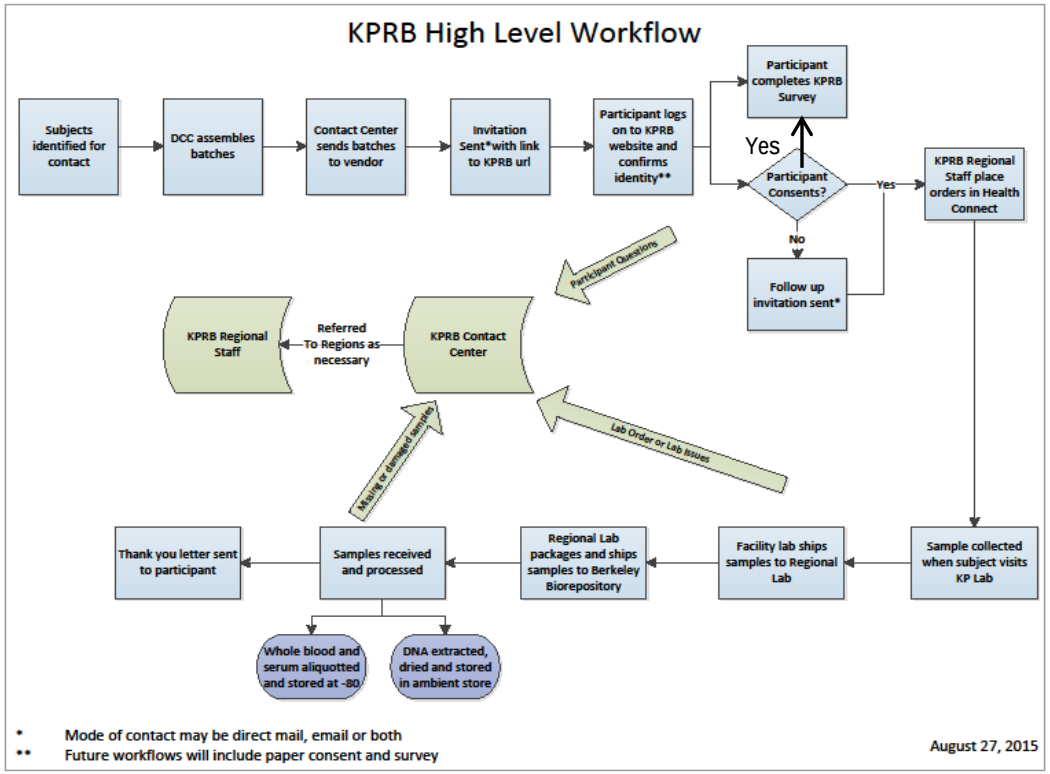
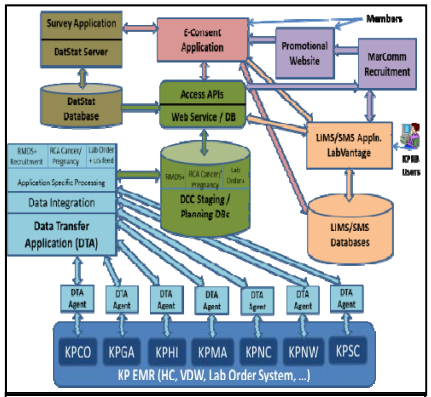
Recruitment Workflow

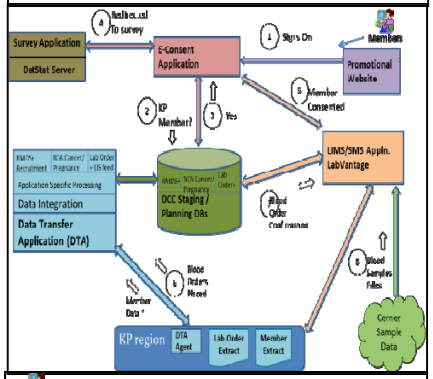


Data Coordination Core

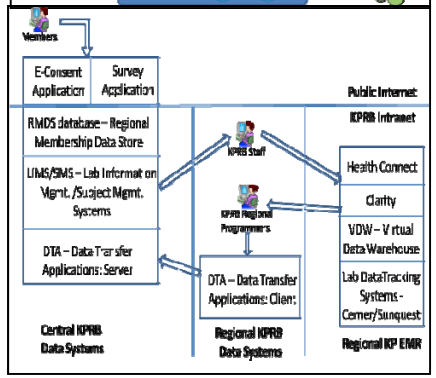
Infrastructure



Data Flow



Recruitment Phase Systems flow



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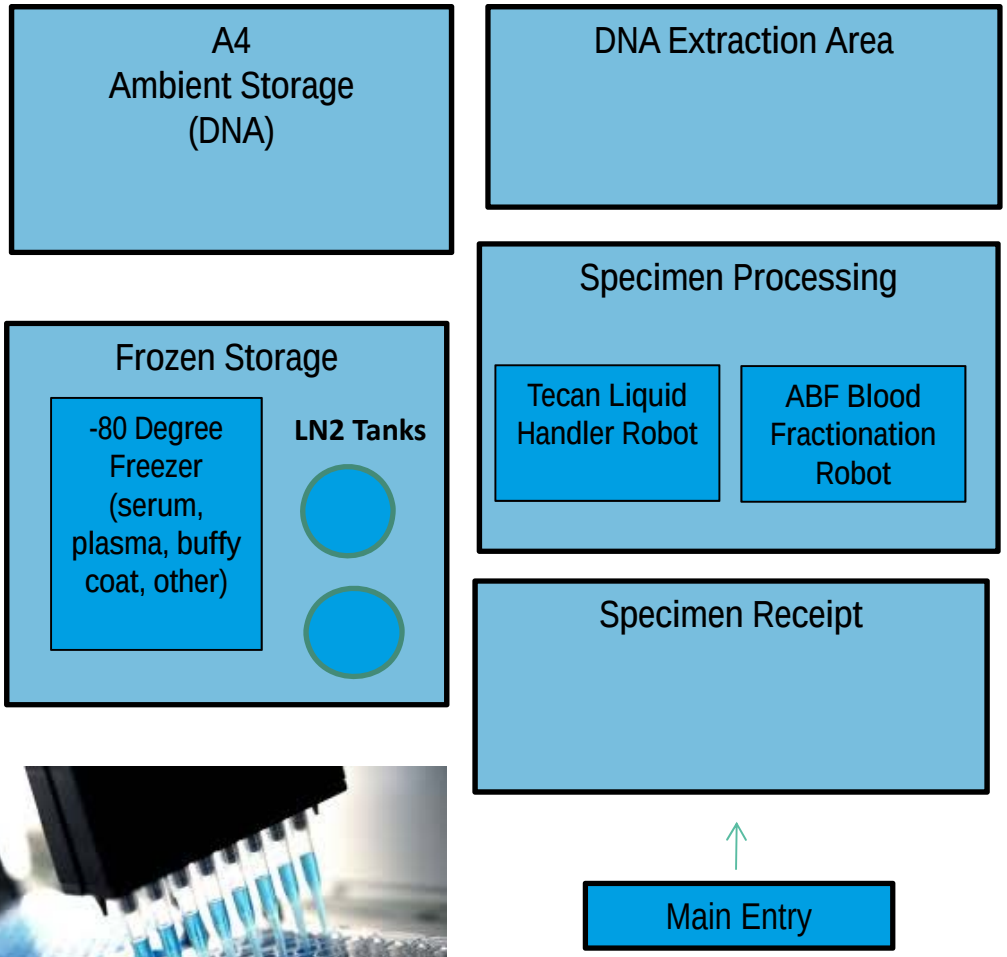
KP Research Bank Biorepository



State of the art equipment and instruments to monitor and maintain sample storage conditions.

Facility includes redundant mechanical equipment, uninterrupted power supply (UPS), 24 hour wireless temperature alarm monitors, 24/7 engineering service and support, liquid nitrogen (LN2) supply as back-up to freezer

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Examples of Regional KP Biobank IRB-approved Projects

Cardiovascular Disease
- GWAS for blood pressure traits/Exome Sequence of Blood Pressure Regulation
- GWAS of Physical Activity and Plasma Lipids

Implementation Studies
- Multi-regional Implementation Study of KRAS Testing in Colorectal Cancer
- Lynch Syndrome Testing Whole Genome Sequencing for Preconception Carrier Status

Cancer genetics and genetic epidemiology
- Breast cancer in Latinas
- Fracture Risk after Treatment for Breast Cancer
- Genetics of Mammographic Density
- Cutaneous squamous cell carcinoma
- Gut microbiome and breast cancer
- Prostate Cancer in African Americans (highest rates in world in Bay Area)

Genetics in other key areas
- Genetics of Host Resistance to Staph Infection
- Multi-Ethnic GWAS and Exome Sequencing of Bipolar Disorder
- Genetics of Glaucoma in African Americans

Pharmocogenetics
- Clinical impact of pre-emptive genotyping for pharmacogenes

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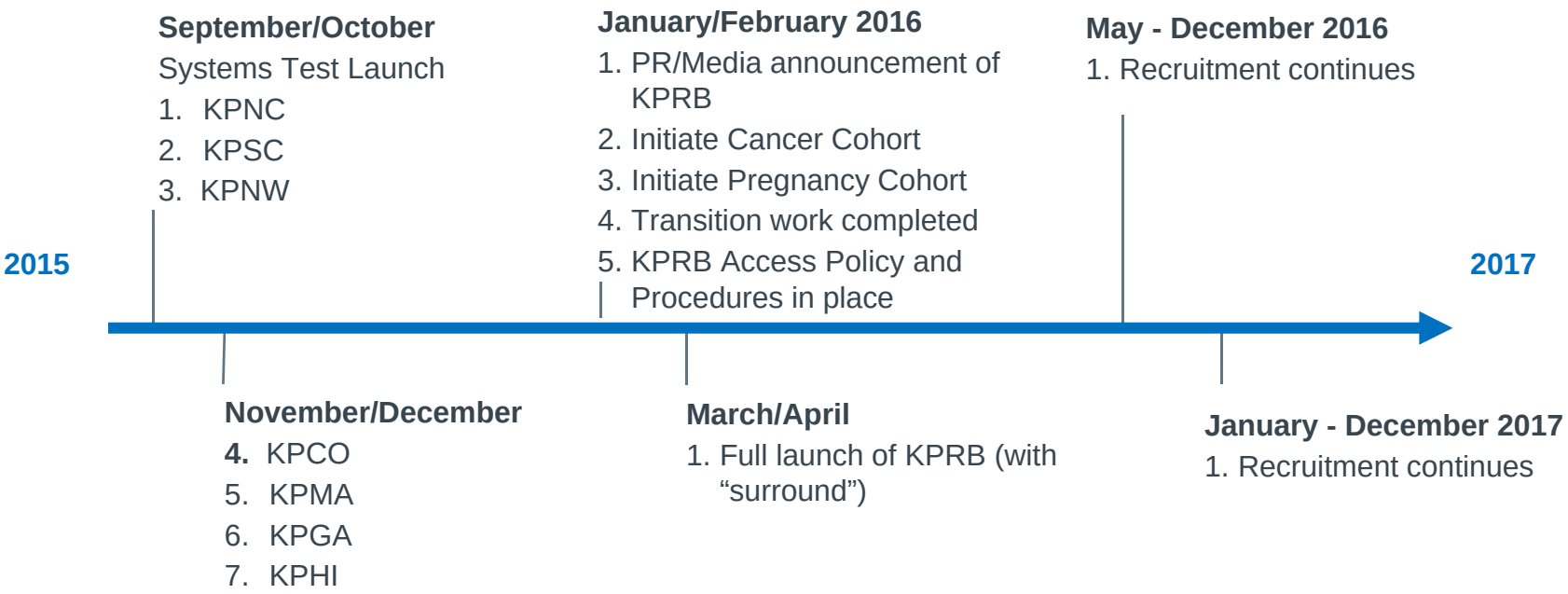
KP Research Bank Timeline



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Collaboration Opportunities

- The KPRB is being built as a resource to support internal KP researcher and collaborations with external researchers
- Access Process:
  - Use of the KPRB typically requires KP collaborator
  - Applications to the ARC
  - Review for feasibility and scientific merit
  - Will be creating data portal so interested investigators can determine if the resource will meet their needs

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