

Kaiser Permanente Research Program on Genes, Environment and Health

California Environmental Contaminant Biomonitoring Program

Scientific Guidance Panel

6 October 2009

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Goals of the RPGEH

- Build one of the largest and most comprehensive resource in the U.S. for research on genetic and environmental influences on health by linking:
 - Clinical data from Electronic Medical Record
 - Participant survey data (over 400,000 KPNC members, to date)
 - Environmental exposure data
 - Genetic information on 500,000 consenting KP members

Goals of the RPGEH

- Enable KP and collaborating scientists to discover and characterize genetic and environmental influences on disease susceptibility, disease course and severity, and response to treatment
- Conduct research to translate findings into improvements in health and medical care
- Conduct research on the ethical, legal and social implications of genetic research and the use of genomic information in medical care

Why Kaiser Permanente?

- Broadly representative & diverse membership
- Large membership means greater potential for studying rare diseases
- HealthConnect (EMR) provides rich, comprehensive, continuously updated clinical data
- Internal research infrastructure experienced in working with KP data and members
- Strong positive (& longitudinal) relationship between KP and members

RPGEH Progress - Phase I

(Jan 2005- Dec 2007)

Funded by private foundations and Kaiser Permanente

- **Informed and engaged KPNC membership** through internal communications, focus groups, and public media relations
- **Organized Community and Scientific Advisory Panels**
- **Built database** -- Organized de-identified electronic clinical data into 12 disease group registries, plus a Healthy Aging cohort
- **Surveyed all adult members** -- to obtain demographic, environmental, and behavioral data

RPGEH Disease Areas of Interest

- Alcohol Use Disorders
- Asthma and Chronic Lung Disease
- Autoimmune Disorders
- Cancers & pre-malignant disease
- Basal and Squamous Cell Skin Cancers
- Cardiovascular Diseases / Events
- Healthy Aging Cohort
- Infectious Diseases (Viral Hepatitis, HIV, Sexually Transmitted Infections)
- Metabolic Disorders
- Neurodegenerative and Movement Disorders
- Psychiatric Disorders
- Reproductive Disorders

RPGEH Survey (2007-2009)

- Survey mailed to 1.9 million adult KPNC members with 2+ years membership
- Chinese and Spanish translations
- 5 page questionnaire includes demographics, health history, family history, smoking, alcohol, diet, physical activity, reproductive history and health
- ~ 400,000 completed (~21% response) to date
- Good representation of diversity of KP membership (36% or >140,000 from minority groups)

RPGEH Goals -- Phase 2

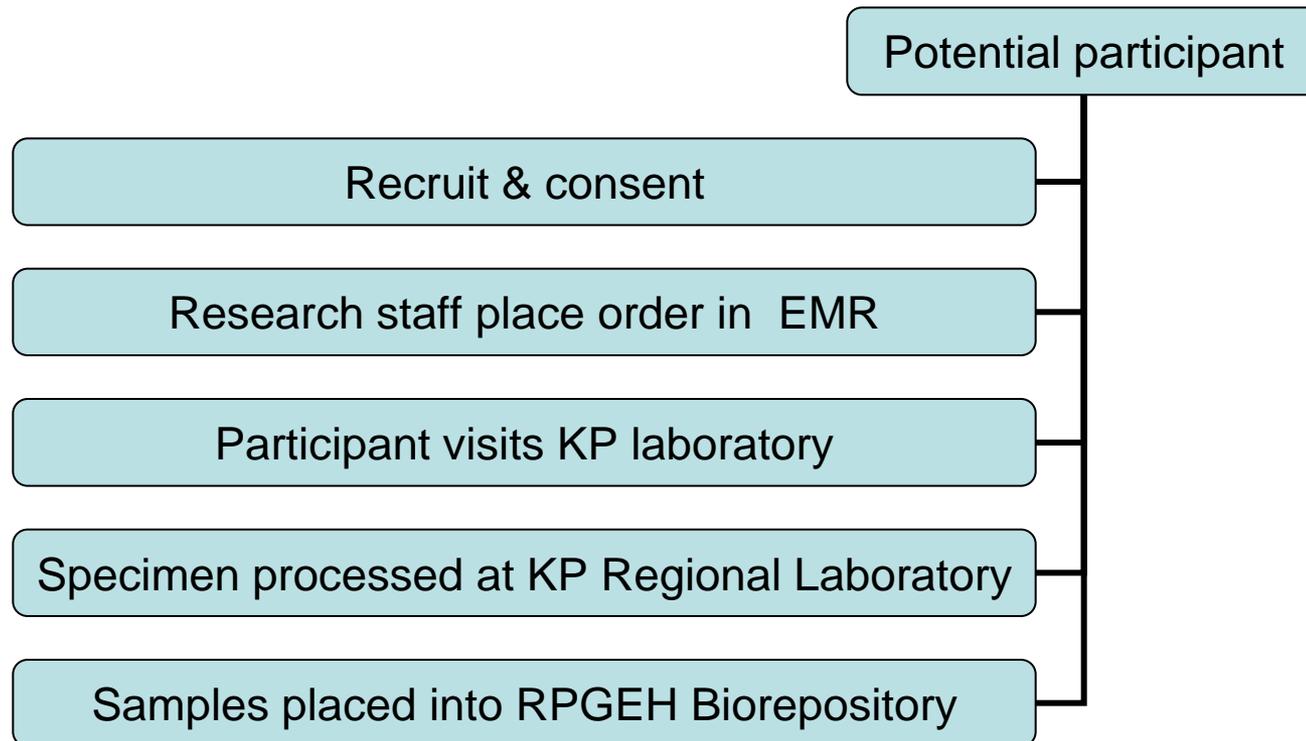
(Jan 2008- Dec 2013)

- **Establish RPGEH Biorepository**
- **Build database of environmental exposures**
- **Develop infrastructure to facilitate research collaborations**
- **Launch research studies**

RPGEH Biorepository

- **Initial goal of 200,000 DNA specimens** (blood or saliva) in 2008-2010 - KP and Foundation support
- Plan to have 500,000 sample biorepository by 2013
- RPGEH Survey Respondents contacted to obtain consent and saliva samples
 - **> 135,000 signed consent forms to date**
 - **> 110,000 saliva samples to date**
- Developing capability to collect blood samples through existing KP clinical infrastructure and Regional Laboratory
- Will collect samples (blood or saliva) from other large cohorts

- RPGEH's goal is 100,000 new blood samples each year through 2013 from consenting Northern California members
- The methods currently used in research are expensive, time-consuming, and inconvenient for members who volunteer.
- Meeting targets will require coordinating with KPNC clinical blood draw system.
- Able to target individuals for inclusion across a variety of factors: disease, age, sex, location, prior participation



- Meeting regulatory requirements
 - IRB
 - Medical practice
- Electronic system impediments
 - Co-pay issues
 - Maintaining research confidentiality
 - Recording of results

- Individual Level Factors
 - Questionnaire data, e.g. smoking, alcohol, physical activity, etc.
 - Clinical ‘Environment’, e.g., health status, drugs, devices, diseases, surgeries
- Social and Built Environment
 - “OurSpace”, a collaboration of DOR/KP, UCSF, and UCB, is creating a “built environment” GIS database
 - Census data
- Toxins/Pollutants Data
 - Developing collaboration with CEHTP
 - Additional toxic / host factors to be measured in biospecimens

Active & New Grants Awarded

Robert Wood Johnson Foundation and KFRI to support development of RPGEH Program and biospecimen collection

- First Research Grants
 - Genome-wide Association Study of Prostate Cancer in African-American Men -- NCI
 - Multi-ethnic Genome-wide Association Study of Bipolar Disorder -- NIMH
 - LACE study of factors influencing Breast Cancer Survivorship -- NCI
 - NIH Grand Opportunity or GO (ARRA) funding to genotype 100,000 individuals

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- What is RPGEH doing that provides a base for collaboration?
 - Specimens
 - Routine

Anticipated RPGEH specimen collection is either saliva or blood (3 tubes; Tiger, lavender and yellow top)
* Ability to modify in specific cases
 - Special

If specimen acquisition protocol out of routine clinical laboratory standards, need to set up separate process
 - Urine

Can be done in clinical laboratory setting
 - Environmental (e.g., soil, household dust, etc.)

- What is sampling strategy
 - Who – what is target population(s)?
 - What – what biospecimen and data are needed?
 - Where – geographic distribution
 - When – season, time of day
 - How many?
 - How often? - are there individuals desired for serial samples?
 - Environmental samples (e.g., soil, household dust, etc.)

- What research & administrative arrangements are needed?
 - Funding
 - If results returned, how will this be done?

- Special opportunities
 - MHC cohort with serum stored between 1964-73.
 - Existing studies at KP with stored serum (PD, ALS, etc.)