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 though 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.
Overview of proposed flow

Potential participant

- Recruit & consent
- Research staff place order in EMR
- Participant visits KP laboratory
- Specimen processed at KP Regional Laboratory
- Samples placed into RPGEH Biorepository
Issues

- Meeting regulatory requirements
  - IRB
  - Medical practice
- Electronic system impediments
  - Co-pay issues
  - Maintaining research confidentiality
  - Recording of results
Development of Environmental Data for RPGEH

- **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
Catherine Schaefer, Ph.D., Executive Director, RPGEH
Neil Risch, PhD, Co-Director, RPGEH
Mary Henderson, Managing Director, RPGEH
Sarah Rowell, MPH, Assoc Dir Research Ops, RPGEH
Larry Walter, MA, Assoc Dir IT and Informatics, RPGEH
Carol Somkin, PhD, ELSI Core
Elize Brown, JD, DrPH Community Outreach and Education
Stephen Van Den Eeden, PhD, Environment Core
Charles Quesenberry, PhD, Biostatistics and Study Design
Lisa Croen, PhD, Biorepository Design Core
Larry Kushi, ScD, Collaborations Core
Joe Selby, MD, MPH, Director, Division of Research, KPNC
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 needed?
Answers to:

- 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.)