

Finding Information on Ongoing Population Studies Supported by NIH Institutes and Centers

Opportunities and Challenges

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Use of Cohort Studies and Clinical Trials for Multiple Outcomes

- Initiating large population-based studies requires enormous investments of funding and staff that may not be possible for all ICs
- Many such studies are already ongoing
- Recruitment and comprehensive phenotypic assessment are greatest initial expenditures
- Addition of risk factor and outcome assessment can be relatively inexpensive
- Whole genome association (WGA) genotyping making multiple uses even more compelling

Goal of Whole Genome Association Studies (WGA)

- Identify genes related to complex diseases
- Complex diseases: caused by multiple genes of small effect, not amenable to family studies
- Whole genome: interrogate all variation throughout genome, two main approaches
 1. Family linkage study with 400 microsatellite markers, assumes ~10mB regions of linkage disequilibrium
 2. Case-control designs with 300-500K SNPs, assumes ~10kB regions of linkage disequilibrium

Availability of Information on Existing Population Studies

- Population studies of selected ICs
 - NCI: Consortium of Cohorts
 - NHLBI: Population Studies Data Base and Limited Access Data Sets
 - NIDDK: Ancillary Studies RFA
- ClinicalTrials.gov
- Repositories of selected ICs
 - NIA - NIDDK - NIMH - Framingham
 - NIDA - NIGMS - NINDS - Others

NCI Consortium of Cohorts

Goal: to address issues of gene environment interactions in cancer etiology for exposures best assessed in a cohort design, such as:

- Compelling hypotheses from laboratory or clinical research that require confirmation through simultaneous testing in multiple cohorts
- Specific genes or gene complexes thought to control a key molecular pathway across a variety of exposures and cancer sites
- Systematic genome-wide investigation of genetic polymorphisms and their interactions with exposures and cancer risk

NCI Consortium of Cohorts (n = 22)

- ACS Cancer Prevention Study-II (CPS-II)
- Alpha-Tocopherol, Beta-Carotene Cancer Prevention (ATBC) Study
- Agricultural Health Study
- Black Women's Health Study
- California Teachers Study
- CLUE I and II
- European Prospective Investigation into Cancer and Nutrition (EPIC)
- Health Professionals Follow-Up Study (HPFS)
- Multiethnic Cohort Study
- NIH-AARP Diet and Health Study
- Nurses' Health Study I - Nurses' Health Study II
- Nutrition Intervention Trials-Linxian
- NYU Women's Health Study
- Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial (PLCO)
- Physician's Health Study
- Shanghai Women's Health Study
- Shanghai Men's Cohort Study
- Shanghai Husbands Cohort
- Singapore Chinese Health Study
- Southern Community Cohort Study
- Women's Health Initiative
- Women's Health Study

<http://epi.grants.cancer.gov/Consortia/cohort.html>

NHLBI Population Studies Data Base and Limited Access Data Sets

Goal: to provide information about ongoing clinical trials and epidemiologic studies, and to distribute limited access data sets on completed trials and ongoing epidemiologic studies

- Descriptions of > 800 clinical trials and epidemiologic studies regularly drawn from ClinicalTrials.gov
- Descriptions, protocols, and procedures for access to data sets from 16 epidemiology studies and 40 clinical trials

NIDDK Ancillary Studies to Major Ongoing Clinical Research Studies

Goal: to increase utilization of NIDDK and NHLBI clinical studies for research relevant to the missions of both ICs through ancillary studies

- Descriptions of 31 clinical research studies in diabetes, digestive, and kidney diseases
- Descriptions of 19 clinical research studies in heart, lung, and blood diseases
- Policies for proposing ancillary studies to existing research studies

ClinicalTrials.gov of NLM

Goal: to provide regularly updated information about federally and privately supported clinical research in human volunteers

- Authorized by 1997 FDA Modernization Act, primarily for lay public and care providers
- Expanded after requirement by International Committee of Medical Journal Editors (ICMJE) for registration of clinical trials in public database by 9/2005 (DeAngelis *NEJM* 2005; 352:2436-8)
- ClinicalTrials.gov approved by ICMJE for this purpose, NIH strongly encouraging registration of phase I-IV trials and observational studies

Studies included in ClinicalTrials.gov

- Studies currently recruiting subjects and those whose recruitment is completed
- Interventional studies (phases I-IV) and observational studies
- Sponsored by NIH, other federal agencies, private industry
- Currently 29,500 clinical studies
- Includes purpose, recruiting status, eligibility, location, contact, study design, phase, disease/condition and treatment

NIH Repositories

- NIA Cell Repository
- NIDA Center for Genetic Studies
- NIDDK Central Repository
- NIGMS Human Genetic Cell Repository
- NIMH Human Genetics Initiative
- NINDS Human Genetics Resource Center
- NHLBI Framingham Heart Study