Multi-IC Symposium on Application of Genomic Technologies to Population-Based Studies

Informed Consent:
The GAIN Framework and Points to Consider

Informed Consent

- Implements the principle of “Respect for Persons”
  - Autonomy of individuals
  - Protection for those with diminished autonomy
- Three components
  - Information
  - Comprehension
  - Voluntariness
- Focus here on the documents more than the “process”

Basic Questions to Consider

- Existing samples or prospective collection?
- Identifiability of the data?
- Scope of data sharing and collaborations planned?
- Plans for potential re-contact?
- Framework for ensuring participant protection?

The Genetic Association Information Network (GAIN)

- A public-private partnership between
  - NIH
  - The Foundation for NIH
  - The private sector: Pfizer, Affymetrix, Abbott
- Goal is to encourage whole genome association studies of common disease
- Sufficient funds now in hand to support genotyping for 7 common disease projects, each with ~1000 cases and ~1000 controls

Guiding Principle of GAIN:

The greatest public benefit will be achieved if results of whole genome association studies are made immediately available

- Genotype and phenotype data will be deposited into a central database and made available for broad research use as soon as quality checks are complete

GAIN Framework for Informed Consent Considerations

- Approval authority for GAIN participation is the local institution
- Participation includes
  - distribution and use of samples for whole genome genotyping
  - broad distribution of genotype-phenotype data through the GAIN Database
- Administrative review of consent forms and any institutional restrictions
- NIH Data Access Committee will implement institutional parameters

GAIN-Appropriate Consent Forms Should Include:

- Use of samples for genetics/genomics
- Collection and distribution of data & health information
- Potential Risks
  - Loss of privacy
  - Stigmatization (individual and community)
  - Discrimination
- No prohibition on commercial use
- Inability to fully withdraw data from use

Elements Applicants Should Consider within Consent Forms:

- Any restrictions on future research use of data or samples, e.g.,
  - to study only specific disorders
  - limitations on data distribution
- Commitment to return individual or aggregate results
- Commitment to re-contact participants if “new information” may influence willingness to participate

Data Access

- Immediate and unfettered access to all qualified researchers provides maximum opportunity for scientific progress
- Must balance access with:
  - need to protect confidentiality of research participants
  - desire to respect autonomous choices of participants
- There is the potential for access by other interested parties
- Can consents for prior studies ever be adequate for open access model?

De-identification

- What personal identifiers should be removed prior to broad data access to adequately protect confidentiality?
- Is extensive genotype or sequence data an identifier (now or in the future)?
- How should potential risks of re-identification be defined for participants?

Returning Results

- Potential risks related to participation significantly influenced by intent to distribute individual results
- Many existing research projects (and consent forms) are predicated on never returning genetic results
- BUT, if samples are not irreversibly de-identified, and information of compelling clinical utility is discovered, is it ethical not to provide findings?
- What should be the threshold for disclosure?

Some Questions to Consider

- Challenges encountered in working with IRBs for genomic applications to population studies?
  - how can those best be addressed?
  - Is IRB approval necessary for access to data or is it an obstruction without protections?
  - How can we encourage centralized IRB infrastructure?
- How to inform subjects of privacy risks/unknown risks associated with public data-sharing (especially of SNP based WGAS)?
- How to assure patient wishes to have data shared broadly is protected?
- How can participant privacy be maximized when individual genetic profiles are placed into public databases?
- How can the risks to groups/communities participating in genomic studies be minimized?
- Can individuals realistically withdraw from a study where data is de-identified?
- Is there practical utility in “nested” (check box) consent forms when broad public sharing of data is expected?

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GAIN Program

GAIN HOME PAGE

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GENETIC ASSOCIATION INFORMATION NETWORK (GAIN)

The Genetic Association Information Network (GAIN) is a public-private partnership of the Foundation for the National Institutes of Health, Inc.(FNIH), which will include corporations, private foundations, advocacy groups, concerned individuals, and the National Institutes of Health (NIH) (Overview). This initiative will take the next step in the search to understand the genetic factors influencing risk for complex diseases. Through a series of whole genome association studies, using samples from existing case-control studies of common diseases, the project will contribute to the identification of genetic pathways that make us more susceptible to these diseases and thereby facilitate discovery of new molecular targets for prevention, diagnosis, and treatment.

GAIN aims to release data as broadly and rapidly as possible, with equal opportunity for access by all potential research users. Unlinked genotypic data will be openly and freely accessible without need for prior approval. Linked genotypic and phenotypic data will be made available to all qualified users at the same point in time and through the same access approval mechanisms with no special access provided to GAIN partners. Appropriate policies and procedures will protect the confidentiality of study participants and recognize the intellectual contributions of the researchers who contribute the samples and the phenotype data to GAIN (Policies and Procedures).

FNIH is actively seeking additional funding Partners to participate in GAIN (Partnerships).

Application for Genotyping Services

Applications from investigators wishing to submit material from existing studies for genotyping will be reviewed by technical experts from academia, government, and industry (Overview). Note that GAIN will not support the collection of new samples, data, or consent. Applications will be submitted through the FNIH's online application site (Instructions for Applicants). Applicants and their institutions will be required to abide by GAIN policies for data access, publication, and intellectual property (Policies and Procedures). Phenotype and exposure data will be submitted directly to the National Library of Medicine's National Center for Biotechnology Information (NCBI). Applicants will be required to provide a copy of the entire data set proposed for whole-genome association study, with a copy of the data documentation, for evaluation purposes only, at the time the application is submitted (Instructions for Applicants).

Projects selected for genotyping will submit DNA samples directly to the genotyping provider at a later date (Genotyping and Analysis).

http://www.fnih.org/GAIN/GAIN_home.shtml

Identifiers Excluded from GAIN Dataset

- Names
- Phone numbers
- Fax numbers
- Electronic mail addresses
- Social security numbers
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers and serial numbers, including license plate numbers
- Device identifiers and serial numbers
- Web universal resource locators (URLs)
- Internet protocol (IP) address numbers
- Biometric identifiers, including finger and voice prints
- Full face photographic images and any comparable images
- Birth date and month
- Geographic subdivision, dates (other than complete birth dates), and "other" identifiers (e.g., outliers) MAY be permissible if relevant to the science