GAIN Human Subjects Protections

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Role of the ACD Working Group (ACD WG) in GAIN Project

Provides advice to the Advisory Committee to the Director, NIH (ACD) on participant and data protection for GAIN

- Source of independent advice
  - Effectiveness of policies
  - Need for amendments
- Functions as Data Use Review Board (DURB) for GAIN

ACD WG supports current GAIN data use procedures

- Integrity of informed consent as cornerstone
- Focus of oversight on data requests that
  - are difficult to resolve
  - are denied

Privacy protection

- Inherent concern for data repository with genomic & phenotypic data

- ACD WG supports request for Congressional statute invoking protection from disclosure under FOIA exemption 3

http://www.usdoj.gov/oip/exemption3.htm

Interface between GAIN and the public

- Need for information for the public
  - In different formats, for multiple venues
  - Explain nature and value of data repositories
- Need for triage mechanism
  - Point of contact (Phone/website/email) with referral to person/agency who can answer the question

Communication with investigators

- Information about GAIN for distribution by submitting investigators
  - Materials that can be sent to participants, as deemed appropriate
- Contact for investigators interested in data use
  - Potentially same triage mechanism as for questions from the public

Issues discussed by ACD WG, not resolved

- Group harm as a potential concern in use of GAIN data
- Appropriate informed consent for prospective enrollment in future data repositories
- Return of results to participants

Group harm - under discussion in bioethics community

- Not addressed in the Belmont Report or necessarily included in beneficence, respect for persons, or justice
- Should we consider 4th principle for research?

  “Respect for communities”
  - obligation to respect values and interests of the community
  - wherever possible, protect community from harms

Emanual & Weijer, Protecting communities in research, in Belmont Revisited, Eds. Childress et al, 2005

Appropriate informed consent for data repository - also under discussion

- Informed consent concept assumes right to decide participation based on full knowledge of study
- Not feasible for data repositories; options include:
  - Meaningful pre-authorization, e.g., for “health-related research”
  - Community consultation
  - Delegation of oversight to appropriate body
  - Periodic re-consent/communication

BMC Medical Ethics 2003; 4: www.biomedcentral.com/1472-6939/4/1;
Lancet Oncol. 2006 Mar;7(3):266-9;
Annu Rev Genomics Hum Genet. 2007;8:343-64.

Return of results - broad range of opinion

Choice not to return clinically meaningful results "...seems, at least in extreme situations, immoral, possibly illegal, and certainly unwise." Greely, Annu Rev Genomics Hum Genet. 2007;8:343-64

"...reporting individual results back to donors who have not requested the results may be a direct violation of their personal integrity." Helgesson et al Nature Biotech 2007;25:973-5.

ACD WG oversight (like other GAIN components): a work in progress

Accumulating experience will

- help to clarify appropriate boundaries for data use
- identify areas for reflection & potential new policy development
- point to strategies for enhancing future data repositories