Responsive Governance: Shifting Ethical Paradigms and Practices for Repositories

Edwards KA1,2,4, Anderson NR3, Fearn PA1,3, & Fullerton SM1,2,4

1Institute of Translational Health Sciences, 2Dept Bioethics & Humanities, 3Dept Medical Education and Biomedical Informatics, University of WA, 4Institute for Genomics & Healthcare Equality

**BACKGROUND**

The challenges of large-scale translational biorepository research require a new and responsive approach to research ethics. The evolving needs of patients, researchers, and institutions are core to advancing and sustaining human subjects’ regulations and research ethics practices. Researchers are:

- Challenged by new demands for data sharing and secondary use
- Often will not have met the contributing patient
- May not have identifiers or protocols that would permit re-contact

Alternative practices are needed to demonstrate respect for participants and build trust in this setting of enforced anonymity.

**EMERGING DATA**

Data shows that the public is concerned about privacy but that they are still willing to donate their data to repositories. People will make their own risk/benefit calculations and will be willing to take risks if the presumed benefit is valued, or the person who is asking is a trusted source.

Because of the wide variability in public values and preferences, having a dynamic, responsive governance mechanism will be critical to the integrity of the system.

2008 randomized public survey of 4659 (Kauffman et al. 2009): 90% were concerned about privacy protections; 60% would participate in a biobank if asked; 48% would provide consent for all research if approved by an oversight board, 42% wanted to be asked for each use; 37% were worried the data could be used against them; 92% would allow academic researchers to use data; 80% “goft researchers”; 75% industry

Receiving research results, or $200, made a difference in interest in participating and lessened concerns about privacy.

Telephone interviews were conducted with 1,193 patients recruited from clinics (Hull et al. 2008):

- 72% wanted to know about research being done with anonymous samples; 81% with identifiable samples
- 37% of reasons for wanting to know about what research was done were curiosity-based.
- 57% would require researchers to seek permission, whereas 43% would be satisfied with notification only.

“Blanket” consent is not meaningful, and from some studies, is also misleading for participants.

Alternatives to blanket, or open, consent include:

- Initial consent to a process for deciding how their samples will be used
- Re-consent for prospective studies without clear consent direction
- Re-contact for participation in new research endeavors possible
- Re-contact when institutional or oversight review identifies new risks

We should explore new methods of re-contact (automated, electronic communication), which:

- Potentially aids in initial recruitment
- Donor involvement in enlisting others
- Keeps participants engaged and informed about repository activities
- Builds and sustains relationships, which are important to trust

**ACCOUNTABILITY**

A research repository governance system will need to build in accountability mechanisms that:

- Track the research uses of repository samples and data (audit trails)
- Develop plans for risk management
- Establish recourses or consequences if breaches occur

Accountability mechanisms may need to evolve at the local (repository-specific), institutional, and national (funding) levels.

Transparency about the systems for accountability will help enhance trust

- Effective communication strategy
- Audit trials through informatics solutions

**RETURN OF RESULTS**

Changing participant expectations suggest repository managers will need to anticipate, and develop systems to support, the routine return of results. The research is needed to determine if participants interests will be best met by the return of individual or aggregate findings:

- Some incidental findings will need to be returned
- Novel bioinformatic approaches may simplify

Open-ended nature of research means that extra effort to maintain contact details will be needed

**SELECTED CITATIONS**

- Greely HT. Unruly ethical and legal underpinnings of large-scale genomic biobanks. Ann Rev Genomics Hum Genet 2007; 8, 343-64.

**ACKNOWLEDGEMENTS**

This research was made possible in part by funding through NHGRI Grant P50 HG003374 (Burke, PI), University of Washington, Center for Genomics and Healthcare Equality; NCRR Grant U1L RR025104 (Diss, PI), University of Washington, Institute of Translational Health Sciences and NLM training grant (NIH NLM RT5s LM07442).