Use of Genetic Biomarkers for PCOR

Please provide any feedback regarding this scenario in the comment form below or by clicking here.

Max Researcher, at the Prestigious University's Genomic Research Institute, plans a study of gene networks within the human genome thought to be involved in metabolic regulation.[i],[ii] The National Human Genome Research Institute fund Max's study and the Institute as part of a broad coalition of U. S. universities and research institutes conducting genomic sequencing to further the study of an array of diseases. Max's study will compare the genes across individuals to identify potentially significant variations that may shed light on mechanisms and risks for metabolic syndromes (e.g., increased blood pressure, insulin regulation, fat storage patterns) associated with serious conditions like heart disease, stroke, and diabetes.[iii],[iv],[v] Max will recruit and collect blood and saliva samples from participants that will allow her to test for genetic biomarkers of interest and combine data from these genetic samples with genetic data obtained from the coalition database; she may collect additional data types (e.g., clinical, environmental). No data whatsoever from HIPAA covered entities are used in this study. Participants volunteer for the study on the basis of responding to public advertising.

Max obtains approval for the study through the University Research Institute's IRB. Under the terms of the federal grant, coalition members must share all data collected under grant funding in order to support each other's research and further the public good (e.g., biomarkers, loci for certain diseases). Therefore, Max will share and obtain data from the other members of the coalition, and sets up data use agreements with these organizations (DUAs). The DUAs clearly outline the consequences for using or sharing the data inappropriately or outside of the bounds defined in the agreement. Patients consent to the study with the understanding that their data will be used for multiple research studies over time. They will not be contacted to renew consent because the IRB judged re-use of the data to be minimum risk since any direct identifiers associated with the data will be removed, and they will not need to provide additional samples. However, the informed consent will inform the participants of any potential risks related to reidentification. For example, Max may have limited ability to protect genetic records from law enforcement in certain situations.

Questions:

- What types of laws, policies or governance structures could be established to address re-identification issues?
- Should consent forms include information about reidentification risk? Is it feasible to include this type of information in consent forms given the technical complexity of the subject?
- How do you allow individuals the opportunity to control what types of research is conducted with their data?[vi]
- By what methods should data be deidentified to minimize risk of reidentification?
- Is it feasible to include DUA's clauses where data subjects are the third-party beneficiaries should patient data be deliberately re-identified by researchers?
- What potential group and individual harms exist even when data is de-identified?[vii]
- Is the possibility of reidentification considered new information since it could lead to an accidental/unauthorized disclosure? If so, should participants be contacted and informed or the potential risk,or even re-consented? Should the DUA even include considerations and subsequent steps for this kind of risk of reidentification?
- What additional data may need to be collected for research that in tandem with genetic biomarker data (clinical, environmental or otherwise) might increase the risk of reidentifiability?
- Should the biospecimen samples be destroyed once researchers collect the data of interest? Is this helpful to protect individuals?

Title	Response
Description	Researcher collects blood and saliva samples to analyze for particular genetic biomarkers related to disease.
Primary actor/participant	Researcher (end-user) using in-house repository
Support actor/participant	Participants, research coalition members
Preconditions	• All data collection, access procedures, and data uses have been approved by the IRB • Consent has been obtained from participants
Postconditions	Ethical best practices are observed for managing and de-identifying genetic data
Alternatives	• The researcher needs to share identifiable information among the coalition, and must ensure authorization or waiver requirements are met • The researcher must collect additional potentially identifiable data (e.g., demographics, environmental data)
Considerations	Resources for contacting and providing indirect benefit to participants
Data Elements Considered	Genetic biomarkers
Purpose of the Data Collection	Research
Purpose of Data Use	Disease-specific genetic analysis
Terms of Transfer to the Data Holders	IRB approval, informed consent

Terms of Transfer to Researchers	IRB approval

[i] International HapMap Project. http://hapmap.ncbi.nlm.nih.gov/thehapmap.html.en
[ii] The McDonnell Genome Institute. http://genome.wustl.edu/projects/detail/1000-genomes-project/
[iii] Department of Health and Human Services. National Human Genome Research Institute. Funding Opportunity: Centers for Common Disease Genomics. http://grants.nih.gov/grants/guide/rfa-files/RFA-HG-15-001.html
[iv] National Institutes of Medicine, National Library of Medicine. Genetics Home Reference. https://ghr.nlm.nih.gov/handbook/genomicresearch?show=all
[v] National Human Genome Research Institute. http://www.genome.gov/27563453
[vi] The Precision Medicine Initiative Cohort Program – Building a Research Foundation for 21st Century Medicine. Precision Medicine Initiative (PMI) Working Group Report to the Advisory Committee to the Director, NIH. September 17, 2015. http://www.nih.gov/sites/default/files/research-training/initiatives/pmi/pmi-working-group-report-20150917-2.pdf
[vii] The Secretary's Advisory Committee for Human Research Protections (SACHRP). http://www.hhs.gov/ohrp/sachrp/index.html

Unknown macro: 'iframe'