IRB and Institutional Considerations When Reviewing Genomic Studies

Under the National Institutes of Health (NIH) Genomic Data Sharing (GDS) Policy, institutions and their Institutional Review Boards, privacy boards, or equivalent bodies (hereafter IRBs) are responsible for assuring NIH that plans for the submission of genomic and phenotypic data from research studies to NIH designated data repositories meet the expectations of the Policy.

Principal Investigators Should Review The Following Guidance From The NIH:
• Points to Consider for Institutions and Institutional Review Boards in Submission and Secondary Use of Human Genomic Data under the National Institutes of Health Genomic Data Sharing Policy [PDF]

Additional Important Risks To Consider
The information below was gleaned and aggregated from various web sources (Sept 2019). The following may not always apply:

| Clinical Laboratory Improvement Amendments (CLIA) | • Currently, the only federal law regarding return of individual genetic testing research results and incidental findings is the Clinical Laboratory Improvement Amendments of 1988 (CLIA), which sets quality standards for all laboratories performing clinical testing. CLIA prohibits the return of individual research results to study subjects unless the tests were physician-ordered and the results were obtained in a CLIA-certified laboratory. |
| Community Approval | • Some communities may require researchers to obtain community approval before seeking consent from potential participants, and some communities have developed resources to help their members consider the major issues that come with participating in research.  
• For Example: For American Indian and Alaska Native communities, for example, the National Congress of American Indians Policy Research Center, in conjunction with the NIH’s National Human Genome Research Institute (NHGRI), developed a resource to provide information about genetics research (read more). |
| Confidentiality And Privacy Risks | • If the donor becomes aware of such information (disease susceptibility), it could lead to emotional distress on her/his part.  
• If such health-related information becomes known to others, discrimination against the donor (e.g. in insurance or in employment) could result.  
• Unwanted notoriety is a potential risk to donors.  
• The risks of harm to individuals will increase if confidentiality is not maintained and/or the number of donors is limited to a very few individuals. Either, or both, of these situations would increase the possibility of a donor’s identity being revealed without his/her knowledge or permission. |
| Criminal Justice | • Personal sequencing will likely impact our concept of personal privacy, as the technology may allow for the possible exposure our unique “code” that we leave behind on every surface we touch. In particular, even if databases storing our personal sequences are protected from the public eye, the DNA that one may discard on a used coffee cup could eventually be used to identify an individual’s |
| Delay In Regulating Developments in Technology | • Some areas of genetic research present issues for which no clear guidance can be given at this point, either because enough is not known about the risks presented by the research, or because no consensus on the appropriate resolution of the problem exists. It is anticipated that the DNA sequence information produced by the Human Genome Project will be used in the future for types of research which cannot now be predicted and the risks of which cannot be assessed or disclosed [OHRP Guidebook]. |
| GINA | • Genetic Information Nondiscrimination Act (GINA) was created to protect the public from discrimination and allay their concerns about the potential for discrimination, thereby allowing individuals to take advantage of genetic testing, technologies, research, and new therapies. (View GINA Guidance). GINA only applies to asymptomatic individuals. |
| Family Members | • Information about family members not involved in the study may be indirectly obtained through the research subject. While genomic research may reveal new information about the research participant's health, the heritable nature of genetic information raises implications for the research participant's relatives as well. Information about family members not involved in the study may be indirectly obtained through the research participant. Furthermore, genomic research using family pedigrees can trace disease history and may reveal family members that are carriers of a disease or will be affected themselves. These indirect results can pose an ethical conflict between a possible duty to warn family members of research participants about health risks and the protection of research participant privacy (www.genome.gov) 
• The IRB may consider whether to include "secondary subjects" in the consent process. |
| HIPAA | • Health Insurance Portability and Accountability Act (HIPAA), Privacy Rule includes rules regarding the return of genetic (Individual Research Results) IRRs and incidental findings (IFs) in non-CLIA certified labs. A HIPAA clause could allow research participants to obtain access to their lab test reports, even if these reports were generated in a non-CLIA lab. 
• HIPAA contains a provision prohibiting employer-sponsored group health plans from denying individuals coverage, charging them higher rates, or varying their coverage based on "genetic information."
• In 2013, as required by the Genetic Information Nondiscrimination Act, the Privacy Rule was modified to establish that genetic information is health information protected by the Privacy Rule to the extent that such information is individually identifiable, and that HIPAA covered entities may not use or disclose protected health information that is genetic information for underwriting purposes. |
| Preimplantation Genetic Diagnosis (PGD) | • Embryos, created via in vitro fertilization (IVF), can now be tested for a number of genetic traits. The results allows prospective parents choose which embryo(s) to implant in a woman’s uterus. |
| Sponsor Requirements | Some study sponsors impose their own requirements.  
|                       | *For Example:* National Human Genome Research Institute (NHGRI) requires that the research that it funds comply with all applicable federal, state, and local laws, which includes CLIA.  
|                       | Affordable Care Act (ACA) prevents health insurers from denying insurance to people with pre-existing conditions, including genetic conditions. Even though people lose GINA-based protection once they begin to exhibit diseases symptoms, then ACA protections begin. The ACA prohibits insurers from not covering someone or charging someone more if they have a pre-existing condition.  |