Policy for Secondary Findings from Next-generation Sequencing Research 4-4-2018

Purpose

Consistent with emerging research norms and clinical care recommendations, all intramural protocols that include human genomic DNA sequencing should include a plan for whether or not, and if so how, they will evaluate and return information about secondary findings

Background

The NIH intramural research program policy on secondary genomic findings recognizes that although there is not yet a general obligation to seek such findings from research-grade sequencing data, there is an obligation and widely endorsed recommendation to offer certain findings from clinical sequencing. Human subjects research in the IRP spans a broad and continuous spectrum from basic research to ancillary clinical care. It is also recognized that the public holds high expectations with regard to the return of health care information from research studies when that information could reasonably be expected to lead to substantial health benefits to the participant. A committee convened by the DDIR deliberated about these issues extensively, and the recommendations of that committee have been previously accepted by DDIR.

Policy

1. Every protocol that includes genomic sequencing should include an explicit discussion of plans to manage secondary genomic findings.
2. The Institutional Review Board should review each protocol's secondary genomic findings plan and determine if the plan to, or not to, evaluate and return such variants is acceptable.
3. Protocols eligible for this review include those that employ sequencing of the genomic DNA for some or all of genes that are currently recommended for return by the American College of Medical Genetics.
4. In making a determination of whether the proposed plan for seeking and returning such variants is acceptable, the IRB should consider the factors and concerns outlined in the published committee report Darnell et al, Am J Hum Genet.
5. The institutes are responsible for providing their investigators with the needed infrastructure for the evaluation and return of secondary findings or contributing to a shared support service for this function.
6. The IRB should determine whether the proposed informed consent process for secondary findings is appropriate. Recommended consent language is available for investigators to use, but it is not required.
7. This policy applies to sequencing activities that are planned in new protocols or proposed to occur subsequent to the next annual review of an existing protocol. There is no expectation that samples sequenced before this policy was in effect would be retrospectively evaluated for secondary findings.