



The National Children's Study

Return of Individual Research Results to Study Participants: Discussion of the Implications of Real Time Analysis for NCS Policy and Practice

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Program Office

Real Time Data Analysis in the NCS



- NCS policy has been that the vast majority of samples and data would be analyzed in a future, unknown timeframe
 - Not all participants' samples to be analyzed within an immediate timeframe
- New prospect of real time analysis may change this policy
 - Real time analysis is being explored through formative research; may or may not become routine throughout NCS

Possible Implications for NCS Return of Results Policy?



- Does the timeframe in which research results become available have implications for
 - which research results should be reported to participants?
 - a change to the NCS return of results policy?
 - a change to NCS human subject protections procedures, such as informed consent forms?

Approach



- Describe current process for reviewing and revising NCS policy on return of individual research results
- Review current NCS policy with respect to the return of individual research results
- Ask whether new policy considerations are raised by the prospect of real time analyses

Scope of this Presentation



- Returning NCS results is salient to many stakeholders, including participants and their communities
- While this presentation focuses on the return of results to participants, we acknowledge the importance of returning results to communities through a transparent and rigorous process
- The process identified by the NCS to return results to participants may inform the development of strategies to return results to communities

Current Process for Developing the NCS Return of Results Strategy



- The independent Study Monitoring and Oversight Committee (iSMOC) determines which, how, and when findings will be reported to affected individual participants and in aggregate to communities
- When the iSMOC identifies an analysis, a standard, and determines if results are clinically actionable, a recommendation is made to the Study Director.
- The Study Director, in consultation with others, determines if and how the recommendation should be implemented.
 - This may include returning results to participants, consulting with and reporting to oversight bodies, revising the study protocol, and revising study design.
- If the NCS Return of Results policy is revised, this information is incorporated into Study materials.⁶

Current NCS Return of Results Strategy: Informed Consent



- The consent process is designed to tell the participant
 - what we would like to collect,
 - why, how we would collect it, how we would protect it,
 - results we can share with them at the time of a given visit, and
 - when and under what circumstances we may contact participants to ask if they would like to receive their individual research results.

Current NCS Return of Results Strategy: Considerations



- The current NCS practice of return of results is informed by:
 - Identification of analyses to be conducted with Study samples
 - Source of analysis (for example, CLIA versus non-CLIA lab)
 - Available clinical and regulatory standards and current practice
 - Timeframe in which some research results can be analyzed and made available for potential reporting
 - Potential health impact of research result based on clinical significance and medical actionability

Categories of Health Impact of Individual Research Results



- Descriptive Health Information
 - Height, Weight
- Clinically Non-significant Health Information
 - Sex, routine copy number variations in genomic DNA
- Clinically Significant Health Information
 - Medically Actionable
 - Not Medically Actionable
- Unknown Clinical Significance
 - Levels of environmental analytes with no agreed upon critical values

Reassessment of Current NCS Return of Results Strategy



- Does the prospect of real time availability of research results necessitate revision to the NCS Return of Results strategy?
- Are there particular analyses currently not being reported due to lack of immediate availability of results?
- Which of these would be addressed by real time analyses?
- If real time analysis were to become part of the NCS design, would it apply to Vanguard Study and Main Study data?



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