Genomic Testing and Disclosure to Minors

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Max Researcher, a doctor and researcher at a Huntington's treatment clinic within Research University School of Medicine, plans to conduct a longitudinal study on the genetic risk factors associated with Huntington's disease. The research goal is to improve understanding of the disease and to explore early treatment options in order to help inform clinicians, patients, and families and improve clinical decision-making/treatment planning. The study will recruit diagnosed Huntington's patients and their first-degree relatives for participation. Researchers are interested in recruiting relatives who manifest the disease, those who are carriers of the mutation and do not manifest the disease, and those who are at risk for carrying the mutation.

Max plans to recruit participants from the community and to contact Huntington's patients currently or formerly seeking treatment at the School of Medicine' s care facilities within the last seven years. The research protocol approved by the IRB includes specific requirements for children and adolescents who are initially consented into the study by their parent or legal guardian. The study was approved for minors since it can potentially improve their outcomes. The protocol requires assent of the minor, if the child has reached a certain age, and consent by at least one parent (see scenario regarding age-related consent). The patient/parent/legal guardian provides an e-signature, giving consent to participate in the study. Participating minors renew assent, and parents renew consent, annually and whenever there is a change in legal status. Minors consent on their own behalf when they reach legal age of consent or may choose to withdraw from the study. Adults are consented at enrollment and annually throughout the study. If a participant of any age withdraws consent, they may choose to remove their data from the sample, or simply decide not to contribute additional data.

At the conclusion of the study, participants will be asked whether they consent to being contacted by other members of the School of Medicine and other interested parties for future research opportunities. In addition, they will be asked whether they consent to the storage and secondary use of their data and /or their biospecimens for future research as part of broad consent.[i]

Max will collect clinical research data (demographics, family history, and clinical information from EHRs) and biological specimens (blood, saliva) from participants. Max and her research staff collect clinical information; biological specimens are collected by the School of Medicine lab technicians and processed by the affiliated lab.

Questions:

- If a minor agrees to enroll, should they have access to their genetic results and risk factors before the age of consent? What are the relevant state laws?
    - What should the protocol be for sharing this information?
    - Should both parents and participating minors have access to the information?
    - What are the different considerations for privacy and protections based on whether the parent manifests versus carries certain disease markers?
    - Is there variation in state laws that govern adolescents' access/electronic access to sensitive data/consent to sensitive research that might limit their participation?
- What are researchers' obligations for the timing, level of detail, and education around the return of participant results?
    - Variations related to participating minors and/or parental preference for participating minors?
    - Variations related to participating family members?
- Are there policies or legal requirements related to the portability of sensitive information? Will the results be available electronically? Will participants be able to share this information electronically, if they so choose? Are researchers obligated to make this information portable /shareable?
- HD mutations predict disease with almost perfect certainty, do considerations change if weakly correlated genetic risk factors are identified? Do considerations change when a disease is medically actionable? If symptoms may only manifest much later in life? If a genetic test result would impact reproductive decisions but not health (i.e. carriers)?
- Which privacy protections are in place to prevent/limit disclosures of risk to external parties (both electronic systems protections and policies and procedures)? Disclosures of disease to external parties?
- Depending on identification of disease vs. carrier status vs. non-carrier status, to whom, if anyone, should this information be disclosed (e.g., primary care provider, specialist)? Should there be procedures that allow participants to express their preferences and how should those be tracked?
- In the event of accidental/unauthorized disclosure to a third party (e.g., primary care provider, family member, educational institution), what protections are in place to prevent discrimination based on risk? Based on disease? (Genetic Information Nondiscrimination Act of 2008 (GINA) applies to only two cases: health insurance and employment; not educational settings, for example).
    - Is it necessary to discuss these policies/gaps as part of the consent process to ensure the participant understands the risks of participating in the research?
        - Loss of autonomy as to when the participant finds out their disease status
        - Conflicts between when a parent wants their child to find out about disease status vs. legal requirements for disclosure
        - Others?
- Due to the genetic and (potential) disease-related information, where should Max house the research data? A separate database? Should it be linked in any way to the patient's existing EHR within the School of Medicine system?
- How should a situation be handled in which a minor wants to know the results, but the parent does not want to give permission for the minor to see the results?
- Should the researchers follow the recommendations of the American Academy of Pediatrics and the American College of Medical Genetics?

Title	Response
Description	Clinical and genetic data submitted by participants, including minors and affected and unaffected relatives of patients, to support a longitudinal study of a serious disease. A researcher submits an approved data analysis protocol for a research study.
Primary actor /participant	Researcher
Support actor /participant	Patients and first-degree relatives who agree to become study participants, Medical Center-based lab

Preconditions	• Research organization and laboratory collect, store, and transfer information in a secure environment. • Researcher has IRB approval to contact eligible patients and—through the patient—interested family members. • Researcher has IRB approval to conduct community outreach. • The researcher stores and manages the data [within a study-related database?] • After initial consent patients reconsent/assent annually. Minors reconsent upon reaching the legal age of consent.
Post conditions	• The researcher collects and analyzes the data for a specific research study. • Patients have the option of making their data, biospecimens, and/or contact information available for future research.
Alternatives	• Genetic condition that has a cure or introduces risks to other people (e.g., cystic fibrosis). • Genetic risk factors and biomarkers with less certainty than Huntington's disease – e.g. Heart Disease factors. • Collection of consent at the end of the study for recontact by the School of Medicine and other interested parties (e.g., pharmaceutical companies that have a new treatment).
Considerations	Risks are to autonomy (as to when you find out) and disclosure about the participant's disease status (does the participant want to know they are at risk)?
Data Elements Considered	A combination of data collected manually and entered into an electronic database/repository (i.e., clinical research data: demographics, family history, clinical information); and lab data from the biological specimens (i.e., blood, saliva). Genetic data about a specific disease.
Purpose of the Data Collection	Improved disease understanding and treatment options; treatment-related data
Purpose of Data Use	Analysis under a specific research protocol
Terms of Transfer to the Data Holders	Consent to the researchers and care to the treatment facility
Terms of Transfer to Researchers	IRB approval and consent

[i] Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators. 76 Fed. Reg. 44512, 44512-53. http://www.hhs.gov/ohrp/humansubjects/regulations/nprm2015summary.html#

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