Genetic Research Guidance: Non-Paternity with Trios

Purpose

This policy provides to the research community on IRB expectations for the potential discovery of non-paternity during the performance of genetic research.

Policy

During the course of genetic research with trios (proband and both biological parents) non-paternity may be discovered.

It is important to consider whether the genetic research analysis is performed in a Clinical Laboratory Improvement Amendments (CLIA) certified lab with the intent to place results in the medical record.

Procedure

Genomic Sequencing for Research Only

If genomic sequencing of trios is being performed purely for research (not placed in the electronic health record (EHR) and not performed in a CLIA certified laboratory), it is reasonable for investigators to state that non-paternity findings will not be disclosed to participants.

If non-paternity is discovered, investigators may tell the subject that the sequencing was inclusive, or that they didn't find anything, both of which are accurate.

The consent should contain a statement regarding potential findings of non–paternity but state that such findings will not be disclosed.

EHR and Genomic Sequencing/ Genetic Testing of Trios for Research

If genomic sequencing or any genetic testing of trios under a research protocol is being placed in the EHR (which means it must also be performed in a CLIA-certified laboratory before disclosure) the consent form should state that if there is non-paternity, it likely would be discovered, and if so it WILL be disclosed.

The rationale is that the finding of non-paternity will impact the interpretation of genomic results from the trio analysis and this information will be placed in the EHR. For this situation the following guidance should be followed:

1. Both parents should be informed that non-paternity will impact the interpretation of genomic sequencing result in the trio analysis.
2. Both parents should be informed that if there is non-paternity, it likely will be discovered and if so, it will be disclosed to both parents.
3. The consent form should include the potential for non-paternity and the disclosure to

both parents if detected. There should be an explicit discussion about this during the consenting process with both parents.

4. The actual method for informing both parents (who gets told first, together etc.) should be up to the clinicians/researchers.

Template Consent Language

Since parents do not receive a separate report, parental sequencing results will not be directly placed in the medical record. However, in the child's report (which is placed in the child's medical record), certain information describing the way that the result called "a variant" is inherited (such as "maternally inherited", "paternally inherited", "de novo", or "not determined") can be used to determine whether a parent also has the variant.

You should be aware that because we are testing family members, we may find out that someone else might have fathered a child. This information can become apparent from the written test result that will be placed in the medical record. The result could also be of importance for the interpretation of the test result in certain cases. For this reason, we will need to disclose results of non-paternity. We will inform both the mother and father. This information will also become part of the medical record. If you wish, you may let us know in confidence if this is a possibility and decide if it would better for your family not to participate or be removed from this study.

In that situation neither you nor your care team will receive the WES result from this study. The clinical team will be expecting those results, so they will get a short communication from the research team to let them know that your family has chosen to withdraw from the research study. The clinical team can then review alternative approaches to genetic testing and what their implications are.

Related Content

None Indicated

Document Attributes

Title	**Genetic Research Guidance: Non-Paternity with Trios**		
Author	Susan Kornetsky	**Dates Reviewed/ Revised**	11/15/2019
Reviewed/ Revised by	Susan Kornetsky		
Copyright	©Boston Children's Hospital, 2020	**Last Modified**	1/20/2020
Approved	Susan Kornetsky, MPH Director of Clinical Research Compliance August Cervini, MBA Vice President for Research Administration		