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| Owner | Susan Kornetsky: Manager |
| Department | Research |
| Applicability | Boston Children's Hospital- Guidelines |

# Genetic Research Guidance: Non-Paternity with Trios Guideline



## Internal Approval

SVP, Research Administration

EVP, Chief Scientific Officer

## Scope

This guideline applies to all Boston Children's Hospital (BCH) licensed locations, BCH operational and clinical departments, and staff (inclusive of W-2 employees, contracted staff, and members of the medical staff irrespective of their appointment category or employer). As applicable, the guideline also applies to foundation practices leasing space at hospital-licensed locations.

## Guideline Statements

This guidance provides the research community the Institutional Review Board's (IRB) guidance for the potential discovery of non-paternity during the performance of genetic research. Of note, this guidance would also pertain to non-maternity (donor egg) but since this would be expected to be known to both parents, the focus is on non-paternity.

- 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 of placing the results in the electronic health record (EHR).

# Process Steps

## Genomic Sequencing Results Not Performed in a CLIA-certified Lab and Not Placed in the EHR

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

1. If genomic sequencing of trios is being performed purely for research (i.e., not performed in a CLIA-certified laboratory and not placed in the EHR) it is reasonable for the investigators to not disclose findings of non-paternity to participants.
2. 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.

## Genomic Sequencing Results Placed in the EHR

If the results of genomic sequencing, or other genetic testing of trios, under a research protocol are performed in a CLIA-certified laboratory and placed in the EHR, the consent form should state that if there is non-paternity it would be apparent in the sequencing results report and **WILL** be disclosed to the participant by the investigators.



The rationale is that the finding of non-paternity will impact the interpretation of genomic results from the trio analysis and be apparent in the report, although not explicity stated in the report. Participants have access to their EHR and thus the implication of non-paternity in the report is discoverable by the participant. 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

*A sequencing report will only be issued for the child and will include the parents' sequencing results. This report will only be placed in the child's medical record and parents sequencing results will not be directly placed in their medical records. In the child's report, certain information describing the way that the result called "a variant", is inherited (such as "maternally inherited", "paternally inherited", "de novo", or "not determined") is based on whether a parent also has the variant.*

*You should be aware that we may find out that one of the parents (usually the father) is not the biologic*

*parent of the child. When this is the father, it is called "non-paternity". This finding could be important for the interpretation of the text result in certain cases. This information will also be apparent on the written test result that will be placed in the child's medical record. For this reason, we will need to disclose results of non-paternity to the parents. We will inform both the mother and father. If non-paternity is a possibility, you may let us know in confidence and you should decide if it would better for your family not to participate or be removed from this study. If you decide to not participate or to withdraw from the study, genetic sequencing of you and your child for this research project will not be performed.*

## Approval Signatures

| Step Description | Approver | Date |
|---|---|---|
| Co-chair Approval | David Davis | 3/1/2025 |
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## Applicability

Boston Children's Hospital- Guidelines