

Leadership Education in Neurodevelopmental Disabilities (LEND) Program  
Westchester Institute for Human Development  
University Center for Excellence in Developmental Disabilities  
And  
New York Medical College  
*Team Project Abstract*  
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**Title:** Mis-Informed Consent: Deficits in the Informed Consent Process Can Be Identified and Remediated Using NIPT as an Example

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**Background:** The informed consent process is a method of documenting that the associated risks/benefits/limitations and alternatives to a procedure have been discussed with a patient without introducing the provider's personal biases. Informed consent for invasive prenatal testing has understandably focused on the risk of infection, miscarriage, and fetal injury. However, less attention has typically been paid to additional factors that can impact a patient's decision-making process. Discussion of these more comprehensive factors (i.e., culture, religion, etc.) during the informed consent process could help healthcare professionals ensure potential parents make the most appropriate and healthy decisions for their families.

*Non-invasive prenatal testing (NIPT)* is a blood test that can currently detect the presence of fetal trisomies 13, 18 and 21 with high accuracy (~99%). While currently considered a "screening" test, the accuracy rate is nearing that of the diagnostic amniocentesis and chorionic villus sampling testing methods, which have an associated risk of miscarriage. With the introduction of NIPT, there is no longer a risk of miscarriage, but it presents a serious risk of misinformed consent regarding whether or not to undergo testing. The American College of Obstetrics and Gynecology (ACOG) Committee Opinion recommends offering this testing to women at increased risk of aneuploidy.

**Objective:** Review the literature available on NIPT, including how the testing protocol is used in medical practice, the accuracy associated with the results of the testing, the modifications to the informed consent process, and the actions families and healthcare providers have chosen in response to the results.

**Method:**

- Discussion
- Brainstorming
- Flowchart
- Literature Review
- Interviews with Experts
- Revision of Goals

**Conclusions:** Based upon an extensive literature review, and in depth discussion with key community partners, it has become apparent that the broad realm of informed consent necessary before NIPT, is neglected in terms of supporting families in identifying the most appropriate course of action for their individual circumstances. Recommendations need to be made to support an appropriate standard of care for health care professionals involved in NIPT, in particular a flexible framework of information and guidance measures to be adjusted to the individual needs and priorities of the subject family.

**Next steps:**

- Revised goal: to fill in identified gaps in the informed consent process for NIPT
- Continue literature review
- Continue communication with community partners and other experts to monitor the emerging issues
- Survey healthcare professionals about their knowledge of NIPT and what they would like to know about NIPT and informed consent
- Develop recommendations to be considered as an appropriate standard of care