## IRB Protocol

Name: Cecilia Mo

Faculty mentors: Dr. Tessa Scripps, Dr. Susan Rosenthal

Title of Project: Predictors of Paternal Intent to Have Newborn Breastfed and His Self-Perceived Role in Breastfeeding in an Urban Community

## 1. BACKGROUND: STUDY PURPOSE AND RATIONALE

The American Academy of Pediatrics recommends that infants be exclusively breastfed for the first six months of life. The benefits of breastfeeding for infants and their mothers have been well-established, yet breastfeeding rates continue to be below recommended goals in the United States. An overwhelming percentage of mothers begin breastfeeding immediately in the postpartum period but do not sustain this practice once they are home. In the United States, 83.2% of mothers started to breastfeed, 46.9% exclusively breastfed through 3 months, and 24.9% exclusively breastfed through 6 months. In New York, a higher percentage of mothers started to breastfeed (85.1%), but exclusivity at 3 months (42.8%) and 6 months (21.4%) were below both national average and Healthy People 2020 targets. Additional disparities exist within minority and low-income populations.

The demands and expectations of breastfeeding can be very stressful on new mothers. This, as indicated by the aforementioned data, often leads to early cessation of breastfeeding or early introduction of formula despite a mother's goal to exclusively breastfeed. While there are a multitude of factors that influence early introduction of formula prior to hospital discharge, it is clear that a lack of physical and emotional support for mothers is detrimental to the breastfeeding process.<sup>4</sup> Studies have shown that fathers can play a critical role in supporting the physical and emotional needs of new postpartum mothers, making them an ideal population to target when trying to promote breastfeeding.<sup>5</sup>

There have been a few studies done internationally that have looked at predictors of paternal involvement in breastfeeding and effect on breastfeeding rates. However, no such studies have been done in Northern Manhattan, an area where the population is predominantly Latino and is considered one of the most economically disadvantaged neighborhoods in New York City. Therefore, the goal of our study is to identify two things in this population:

- 1) Factors that predict a father's intent to have his newborn breastfed, and;
- Of the fathers who intend to have their newborns take in any amount of breast milk, factors that predict the belief that they should play a role (emotional and/or physical) in breastfeeding.
- 2. STUDY DESIGN AND STATISTICAL PROCEDURES: Our study will take place in the Well Baby Nursery at Morgan Stanley Children's Hospital. A convenience sample of men who meet eligibility criteria (see below under "Study Subjects") will be recruited. The survey is designed so that a score for each category can be obtained. T-tests will be used to analyze the data.
- 3. STUDY PROCEDURES: We will be gathering and analyzing survey data provided by recruited subjects.
- 4. STUDY DRUGS OR DEVICES: Not applicable.
- 5. STUDY QUESTIONNAIRES: The survey will contain questions pertaining to the following categories:
  - a) Demographics
  - b) Breastfeeding history of current newborn and all other children
  - c) Father's perception of social support for breastfeeding
  - d) Knowledge of breastfeeding
  - e) Attitudes towards breastfeeding
  - f) Intent to have current newborn breastfed

    \*\*Only fathers who intend on having their current newborn take in any amount of
    breast milk will answer questions in categories g and h\*\*
  - g) Father's self-efficacy in breastfeeding
  - h) Father's belief that he should play a role in breastfeeding
- 6. STUDY SUBJECTS: A convenience sample of men who self-identify as the "father" for an infant will be recruited. Fathers of full-term (>37 weeks of gestation) singletons are eligible to participate. The self-identified "father" must be present in the postpartum room at time of recruitment and must intend to be primary male caregiver of the newborn.
- 7. RECRUITMENT: A physician and/or research assistant will approach fathers in the Well Baby Nursery to determine basic eligibility for the specific study using a script. If the father is an eligible candidate, the study will be explained using a script. The subject will be explicitly told that participation in the study is optional.
- 8. CONFIDENTIALITY OF STUDY DATA: The questionnaire does not collect identifying information of individual subjects.

- 9. POTENTIAL RISKS: There is no clinical risk to the subject.
- 10. POTENTIAL BENEFITS: There are no immediate benefits to the subjects in this study. The information obtained from this study may inform the design of a potential intervention in an effort to increase breastfeeding rates.
- 11. ALTERNATIVES: Not applicable.

## REFERENCES:

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- 6) Glassman ME, McKearney K, Saslaw M, Sirota DR. Impact of breastfeeding self-efficacy and sociocultural factors on early breastfeeding in an urban, predominantly Dominican community. Breastfeed Med. 2014;9(6):301–307. doi:10.1089/bfm.2014.0015