



University of Puerto Rico  
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Endowed Health Services Research Center  
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**Title:** Prospective Assessment of Intrauterine Zika Exposure, an Integrated Approach

As a neurotropic virus, Zika has been demonstrated to affect the development of the Fetus. The natural history of the effects of the exposure and the mechanisms behind the altered development described in epidemiologic studies still requires further evaluation at different levels. The rapid spread of Zika cases in Puerto Rico has interested many specialist, because of its significant threat to pregnant women and their developing fetus. Although efforts have been made to develop specialized centers of care for affected women, due to the sensitive nature of the problem it is highly likely that women affected by Zika during pregnancy will choose to continue care with their primary provider in the community with the assistance of the Maternal Fetal Specialist as recommended by current treatment guidelines. We have developed this process of data and sample collection to be piloted in a community hospital in recognition of the need to achieve consistent documentation of the exposure and clinical outcomes in the newborn. Our specific aim is to pilot an integrated and standardized data and sample collection process through the collaboration of RCMI investigators that can be implemented in delivery hospitals throughout the Island.

The project is targeted to pregnant women either Zika positive or negative, the negative subjects being the control group. All participants will attend an initial visit where nutritional and environmental exposure surveys will be given and a clinical assessment will be done. The clinical assessment consisting of a clinical examination for the newborn and different sample collections. These sample collections being: blood, urine, vaginal swab, saliva and toenail samples during the antenatal period. A second set of samples will be collected during the admission for delivery including: maternal blood, placental tissue, cord blood, and cord tissue samples. We will also collect maternal and newborn saliva samples within the first 24 post-delivery. In the event that the cord blood cannot be collected according to the sample collection protocol, infant blood samples will be requested to the treating physician. We are currently requesting permission to expand the recruitment phase to include families within the 3 months after delivery to provide the opportunity of comprehensive infant assessment including a neurological scale, and biological sample collection from parents and the newborn. We will also ask participants recruited during that period to share information regarding the access of care provided after discharge from the Hospital.

Apart from our specific aim, we are hoping to create a network of specialists whom have contact with these patients in their daily basis. The Zika crisis has affected many woman and their infants, for this matter we are hoping you could join our team. As part of the partnership, Zika positive patients who have already delivered can benefit from follow up visits with specialists and a detailed infant evaluation at an early stage allowing them to also benefit of participation in future projects.

Cordially,

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