

October 24, 2008

Rohan Hazra, M.D.

Pediatric, Adolescent and Maternal AIDS Branch Center for Research for Mothers and Children Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) National Institutes of Health 6100 Executive Blvd., Room 4B11 Bethesda, MD 20892-7510

RE: Permission to share PACTG/IMPAACT data with PHACS

The IMPAACT leadership and the protocol teams have approved your request to obtain data from the following studies: P1025, 247, 316, P1045, P1055, P1057, 076, 152, 185, 225, 227, 230, 239, 254, 300, 310, 326, 330, 345, 353, 354, 382, 394, P1010, P1022, P1024, P1039, P1047

It is noted that the data requested is:

For any perinatal treatment trial or other study which enrolled mothers of PHACS subjects:

- maternal ART during pregnancy
- maternal viral load, CD4 and concomitant medication use during pregnancy
- maternal toxicology screen results during pregnancy
- maternal illicit drug use (if collected by questionnaire or other means than tox screen)
- complications/infections during pregnancy
- pregnancy/delivery information (gestational age, apgar scores, birth weight, type of birth (C-section, vaginal))

For any IMPAACT study which previously enrolled PHACS subjects (infected or uninfected):

- subject non-ART prior to enrollment in PHACS (OI treatment/prophylaxis meds since birth)
- subject ART since birth (neonatal prophylaxis, for uninfected)
- subject's viral load measures since birth (for infected only)
- subject's lymphocyte subset measures since birth (for infected only)
- any diagnoses since birth
- height/weight measurements since birth
- past neuropsych evaluations (i.e., WISC, WPPSI, Bayley, etc)

Sincerely,

Brooks Jackson, M.D. IMPAACT SOC/NEC Chair

Brooks Jackson

Cc: Paige Williams, Ph.D. Terry Fenton, Ed.D.