

A. COVER PAGE

Project Title: The Impact of Early Medical Treatment in Transgender Youth	
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Program Director/Principal Investigator Information: JOHANNA L OLSON , BS MS MD Phone number: (818) 679-6757 Email: jolson@chla.usc.edu	Recipient Organization: CHILDREN'S HOSPITAL OF LOS ANGELES 4650 Sunset Boulevard Mailstop #97 LOS ANGELES, CA 900276062 DUNS: 052277936 EIN: 1951690977A1 RECIPIENT ID: 8011-RGF009152-00
Change of Contact PD/PI: N/A	
Administrative Official: NAGHMA AHMAD 4650 Sunset Blvd, MS# 97 Los Angeles, CA 900276062 Phone number: 323-361-8560 Email: nahmad@chla.usc.edu	Signing Official: KAREN SUE NIEMEIER 4650 Sunset Blvd. #84 Los Angeles, CA 90027 Phone number: 3233616309 Email: kniemeier@chla.usc.edu
Human Subjects: Yes HS Exempt: No Exemption Number: Phase III Clinical Trial:	Vertebrate Animals: No
hESC: No	Inventions/Patents: No

F. CHANGES

F.1 CHANGES IN APPROACH AND REASONS FOR CHANGE

Not Applicable

F.2 ACTUAL OR ANTICIPATED CHALLENGES OR DELAYS AND ACTIONS OR PLANS TO RESOLVE THEM

In order to completely capture the impact on all youth undergoing treatment with GnRH agonists, recruitment will be expanded to include those youth in Tanner 4 of development. In addition, the minimum age for the cross-sex hormone cohort inclusion criteria was decreased from 13 to 8 to ensure that a potential participant who could be eligible for cross-sex hormones based on Tanner Staging would not be excluded due to age alone. The Principal Investigators assert that this will not impact the data analysis and results of the research study.

Due to the substantial burden on participants for completing the DISC, the Principal Investigators and Co-Investigators decided to stop utilizing the DISC and implement the Mini International Neuropsychiatric Interview (M.I.N.I.) and the M.I.N.I. for Children and Adolescents (M.I.N.I. Kid), version 7.0.2 for DSM-5, as a replacement. This transition means that there is a portion of participants for whom we are missing the baseline diagnostic data due the time it takes for coordinating center and local IRBs to approve the transition in instruments.

F.3 SIGNIFICANT CHANGES TO HUMAN SUBJECTS, VERTEBRATE ANIMALS, BIOHAZARDS, AND/OR SELECT AGENTS**F.3.a Human Subjects**

File uploaded: F3a Human Subjects.pdf

F.3.b Vertebrate Animals

No Change

F.3.c Biohazards

No Change

F.3.d Select Agents

No Change