DRUG DEVELOPMENT TOOL
21CC Transition
DDT COA #000080

San Keller, PhD
Principal Investigator, PROMIS Network Center
American Institutes for Research
100 Europa Drive
Chapel Hill, NC 27517

Dear Dr Keller:

Thank you again for agreeing to continue your ongoing clinical outcome assessment (COA) development effort under the process articulated in section 507 of the Federal Food, Drug, and Cosmetic Act as added by the 21st Century Cures Act (section 507 process). The section 507 process includes three submission types; 1) a Letter of Intent (LOI), 2) a Qualification Plan (QP), and 3) a Full Qualification Package (FQP).

As part of this transition to the section 507 process, the next step for your project, DDT COA #000080: PROMIS® Fatigue for myalgic encephalmyelitic, chronic fatigue syndrome, and systemic exertional intolerance syndrome (ME/CFS/SEID), would be the development of a QP. The QP is a submission that was not part of the legacy process. You may view the COA Qualification Plan outline at: www.fda.gov/media/123245/download.

Under the new process, all three stages are mandatory and all projects undergoing qualification must progress through the stages sequentially.

Please contact the CDER COA Qualification Program at COADDTQualification@fda.hhs.gov should you have any questions (refer to DDT COA #000080).

Sincerely,

Kimberly W. Chiu -S

Digitally signed by Kimberly W. Chiu -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000813833, cn=Kimberly W. Chiu -S
Date: 2019.09.05 06:18:03 -04'00'

Kimberly Chiu, PharmD
Regulatory Project Manager
Clinical Outcome Assessments Staff
Office of New Drugs
Center for Drug Evaluation and Research