WIRB-Copernicus Group Companies

Certificate of Action

Board Action Date: 10/02/2018	**Work Order Number**: 7-1117899-1
Sponsor: SUNOVION PHARMACEUTICALS INC.	**Protocol Approval Expires**: 09/05/2019
Sponsor Protocol Number: SEP361-203 **Amended Sponsor Protocol Number:**	**Continuing Review Frequency**: Annually
IRB Tracking Number: 20162518	**Panel**: 18
Protocol Title: A Randomized, Parallel-group, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of SEP-363856 in Subjects with Parkinson's Disease Psychosis	

THE FOLLOWING ITEMS ARE APPROVED:
Patient Brochure dated 12 September 2018 [V02] #16590972.1 - As Submitted
Patient Poster dated 12 September 2018 [V02] #16590973.1 - As Submitted
Website Communication - Study Description #22820142.0 - As Submitted

Please note the following information about this review:
NOTE: The IRB currently has SEP-363856 Drug Brochure (11-27-2017, Version 7.0) with summary of changes on file.

ALL IRB APPROVED INVESTIGATORS MUST COMPLY WITH THE FOLLOWING:

Consistent with AAHRPP's requirements in connection with its accreditation of IRBs, the individual and/or organization submitting shall promptly communicate or provide, and where necessary cause each investigator to promptly communicate or provide, the following information relevant to the protection of human subjects to the IRB in a timely manner:

- Upon request of the IRB, a copy of the written plan between sponsor or CRO and site that addresses whether expenses for medical care incurred by human subject research subjects who experience research related injury will be reimbursed, and if so, who is responsible in order to determine consistency with the language in the consent document.
- Any site monitoring report that directly and materially affects subject safety or their willingness to continue participation. Such reports will be provided to the IRB within 5 days.
- Reports from any data monitoring committee, data and safety monitoring board, or data and safety monitoring committee in accordance with the time frame specified in the research protocol.
- Any findings from a closed research when those findings materially affect the safety and medical care of past subjects. Findings will be reported for 2 years after the closure of the research.

Federal regulations require that the IRB conduct continuing review of approved research. You will receive Continuing Review Report forms from this IRB when the expiration date is approaching.

Thank you for using this WCG IRB to provide oversight for your research project.

DISTRIBUTION OF COPIES:
Contact, Company
Pamela Vacaflores, MS, Quintiles, Inc.
Kathleen Belvin, Quintiles
Ebony Jackson, Quintiles, Inc.
Christina Wegerski, Quintiles, Inc.

This is to certify that the information contained herein is true and correct as reflected in the records of this IRB. WE CERTIFY THAT this IRB IS IN FULL COMPLIANCE WITH GOOD CLINICAL PRACTICES AS DEFINED UNDER THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) REGULATIONS, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) REGULATIONS, AND THE INTERNATIONAL CONFERENCE ON HARMONISATION (ICH) GUIDELINES.

Association for the Accreditation of Human Research Protection Programs, Inc. — Full Accreditation

Investigator List

These Board Actions apply to the following investigators:

Bhatia, Perminder
Goldstein, Mark
Goodman, Ira
Isaacson, Stuart
Klos, Kevin
Maddux, Brian