Certificate of Action

Board Action Date: 08/12/2019	**Work Order Number**: 1-1195710-1
Sponsor: SERATRIALS, LLC	**Protocol Approval Expires**: 09/07/2020
Sponsor Protocol Number: 2010-017 **Amended Sponsor Protocol Number:**	**Continuing Review Frequency**: Annually
IRB Tracking Number: 20161665	**Panel**: 4
Protocol Title: Prospective Collection of Biological Specimens from Subjects Presenting at Specimen Donation Centers for Research	

THE FOLLOWING ITEMS ARE APPROVED:
Prospective Collection of Biological Specimens from Subjects Presenting at Specimen Donation Centers for Research

Please note the following information about this review:

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.

For Investigator's Brochures, an approval action indicates that the IRB has the document on file for the research.

If the board approves a change of Principal Investigator - Once approved, the new Principal Investigator is authorized by the IRB to carry out the study as previously approved for the prior Principal Investigator (unless the Board provides alternate instructions to the new Principal Investigator). This includes continued use of the previously approved study materials. The IRB considers the approval of the new PI a continuation of the original approval, so the identifying information about the study remains the same.

For research subject to continuing review, 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
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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.

Investigator List

These Board Actions apply to the following investigators: