Cleveland Clinic Institutional Review Board (IRB)
Federalwide Assurance (FWA 00005367)

Cleveland Clinic

August 11, 2020

Ashok Agarwal, Ph.D.

RE: IRB# 20-855: Online Survey on Male Infertility and Antioxidant Use

Dear Dr. Agarwal:

Your new study application received on 8/7/2020 was **approved** under expedited review on 8/11/2020 as **Exempt Research**.

This is minimal risk research using/involving research only includes interactions involving educational tests, surveys, interviews, public observation AND information is recorded with identifiers or codes linked to identifiers and the IRB conducts Limited Review.

The documents reviewed include: New Study Application and Protocol 8/7/20, Survey Form, Information Sheet/Cover Letter, and Approval to use SELECTSURVEY 8/7/20.

The stamped approved documents are available online under the Approved Documents tab. Any additional variables you propose to collect must be submitted to the IRB for review and approval prior to collection.

Alteration Language
A waiver or alteration of written consent and waiver of HIPAA Authorization is approved with the use of an Information Sheet. Access to PHI by the research team is allowed however, sharing or releasing identifiable data to anyone other than the study team is not permitted without additional IRB approval

Changes or amendments that would impact the exempt status of this project require IRB review and approval prior to implementation. Unanticipated problems including adverse events and deviations are to be reported in accordance with IRB Policy 60: Adverse Events and IRB Policy 70: Unanticipated Problems.

Continuing review is not required for this research, but there will be alternative reporting requirements which the IRB will relay via correspondence.

Please note that human subjects research at Cleveland Clinic has been impacted by COVID-19. The study team is responsible for compliance with the enterprise-wide restrictions related to research. This information is available on the Intranet, including the Center for Clinical Research homepage.

The PI is responsible to ensure research team members are knowledgeable of the study protocol and appropriately trained.

If you have any questions regarding study changes or modifications, please call the IRB office at 216-444-2924.

Sincerely,

Bridget Howard, Esq., CIP
Executive Director, IRB and Human Research Protections

BH/sls

This letter is available online under the Correspondence tab

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