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## Work Instruction

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**WI No.:** REDOX- 304-R01

**Title:** Study Treatment Code Unblinding

**Referenced SOP:** Study Treatment Code Unblinding #304-01, SAE Recognition and Reporting #302-00, Data Monitoring Committee # 407-00.

**Author:** Rupinder Dhaliwal, Project Leader      **Signature:** \_\_\_\_\_      **Date:** \_\_\_\_\_

**Intended Audience:** Methods Centre, Participating Research Sites

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### Procedures

The purpose of this operating procedure is to clearly outline the algorithm for unblinding the study participant treatment code for the REDOX<sup>SM</sup> study.

As established by the Sponsor and the Steering Committee, the investigational products used in the REDOX study<sup>SM</sup> are nutrients that are not associated with risks and there are no antidotes to the nutrients. Hence, in the event of an adverse event or medical emergency or accidental administration of the study supplements to a patient not participating in the study, the treatment of the patient is not dependent on the knowledge of the study treatment code. It has been established by the Sponsor and the Data Monitoring Committee (DMC) for the REDOX<sup>SM</sup> study that Code breaking (or unblinding) procedures will only be requested by the DMC (refer to DMC charter SOP # Data Monitoring Committee # 407-00).

- (1) The DMC may request that the Code be broken (or unblinded) in the event that safety issues arise from the aggregated blinded data presented to the Data Monitoring Committee (as per established criteria for unblinding). The aggregated blinded data is to be presented to the DMC at periodic intervals according to established procedures.
- (2) Treatment codes stored at the Methods Centre will be stored in a secure location. The treatment codes are kept in a sealed envelope with the Biostatistician at the Methods Centre who is delegated by the Sponsor to perform this task. Staff involved in the study design, execution and analysis are not permitted access to the codes. The Biostatistician will provide the sealed envelope to the DMC in the event that the criteria for unblinding have been met.
- (3) In the event that the research site is concerned about the well being of the research participant and wishes to break the code (unblind), they will be instructed to contact the Project Leader at the Methods Centre.
- (4) The Project Leader will discuss the need to unblind with the site to ensure the treatment code is not broken unnecessarily. In the event that the breaking of the treatment code is felt to be necessary by the Project Leader, the research site will be asked to discontinue the study supplements. They will also be instructed to follow the established procedures for reporting Serious Adverse Events to the Methods Centre.
- (5) Any discussions between the research site and the Methods Centre will be documented.
- (6) If the treatment code is broken by the DMC, the following must be documented by treatment arm:



- a. Date and time the treatment code was broken
  - b. Individual who revealed the treatment code
  - c. Reason for breaking the treatment code
  - d. Study treatment allocation
- (7) All local REBs must be notified of any situation where it was necessary to reveal the patient's treatment allocation.