

**VA NORTHEAST OHIO HEALTHCARE SYSTEM  
Louis Stokes Cleveland DVAMC  
Medical Research Service  
Subcommittee on Research Safety Policy**

**Effective Date: July 8, 2020**

**SOP Title: SUBCOMMITTEE ON RESEARCH SAFETY MEMBERSHIP**

**SOP Number: SRS--026**

**SOP Version: .02**

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1. **PURPOSE:** To establish membership criteria for those who serve on the Subcommittee on Research Safety.
2. **POLICY:** Membership on the Subcommittee on Research Safety must be constituted according to the criteria outlined within this standard operating procedure.
3. **DEFINITIONS:**
  - a. SRS – Subcommittee on Research Safety
  - b. RSC – Research Safety Coordinator
  - c. R & D – Research and Development
  - d. Candidate – Individual being considered for SRS membership
  - e. Voting Members – Members who cast a deciding vote during convened SRS meetings.
  - f. *Ex-officio* Members – Members who have an interest in or are involved with Medical Research by virtue of their position at the Louis Stokes Cleveland DVAMC.
  - g. Quorum – Fifty-one percent of the voting members present when a vote is taken at a convened SRS meeting.
  - h. SOP – Standard Operating Procedure
  - i. Louis Stokes Cleveland DVAMC – Louis Stokes Cleveland Department of Veterans Affairs Medical Center
  - j. IRE – Institutional Review Entity: A committee that is responsible for the effective oversight of Dual Use Research of Concern (DURC): 15 agents that have the potential to pose a severe threat to human, animal, or plant health, or to animal or plant products.

4. RESPONSIBILITY:

a. RSC:

- (1) Sends out a notice to research personnel when an opening on the SRS exists, which will include an attached copy of this SOP.
- (2) Contacts current SRS members when their appointments are due to expire and confirms if current member volunteers to serve for another one or three-year appointment.
- (3) Confirms permission from candidate's employer (Principal Investigator, Doctor, etc.) that candidate is permitted to serve on the SRS.
- (4) Forwards candidate or re-appointee *curriculum vitae* to SRS members as part of their monthly SRS meeting packet.
- (5) Presents candidate or re-appointee's *curriculum vitae* at a convened SRS meeting.
- (5) Forwards *curriculum vitae* for candidate or re-appointee to the R & D Committee, when approved by the SRS.
- (6) Forwards approval notice to the candidate or re-appointee when the Medical Center Director's approval notice is received from the R & D Coordinator.

b. CHAIR/ALTERNATE CHAIR:

- (1) Review *curriculum vitae* for candidates and/or re-appointees.
- (2) Review SRS SOP Subcommittee on Research Safety Membership to ensure that candidates and/or re-appointees meet the qualifications outlined in Section 5, Procedure, below.

c. R & D COORDINATOR:

- (1) Presents SRS candidates and re-appointees at convened R & D Committee meetings.
- (2) Forwards an approval notice to the Medical Center Director for his/her approval when approved by the R & D Committee.
- (3) Forwards to the RSC the signed Medical Center Director's approval when a candidate or re-appointee has been officially appointed or re-appointed to serve on the SRS.

d. VOTING MEMBERS:

- (1) May nominate potential candidates when an opening occurs on the SRS.
- (2) Review *curriculum vitae* for candidates and/or re-appointees.

- (3) Review SRS SOP Subcommittee on Research Safety Membership to ensure that a candidate and/or re-appointee meet the qualifications outlined in Section 5, Procedure, below.
- (4) Submit any questions or concerns regarding candidates and/or re-appointees prior to the next convened SRS meeting.
- (4) Vote to approve or disapprove a candidate or re-appointee at a convened SRS meeting when quorum is met.

e. *Ex-OFFICIO* MEMBERS

- (1) May nominate potential candidates when an opening occurs on the SRS.
- (2) Review *curriculum vitae* for candidates and/or re-appointees.
- (3) Review SRS SOP Subcommittee on Research Safety Membership to ensure that a candidate and/or re-appointee meet the qualifications outlined in Section 5, Procedure, below.
- (4) Submit any questions or concerns regarding candidates and/or re-appointees prior to the next convened SRS meeting.

5. PROCEDURE:

a. MANDATORY VOTING MEMBERS

- (1) Must include a member of the local Institutional Animal Care and Use Committee, a representative from the facility Infection Control Department, and the facility Radiation Safety Officer.
- (2) Review materials to be presented at convened SRS meetings.
- (3) Have three-year appointments.
- (4) Also have a three-year appointment on the Institutional Review Entity (IRE).

b. OTHER VOTING MEMBERS

- (1) Include the SRS Chair.
- (2) May also include a Clinical Research Coordinator, a Rehabilitation R & D Representative, and a Biological Science Laboratory Technician.
- (3) Must have a VA appointment or Without Compensation (WOC) appointment with the Louis Stokes Cleveland DVAMC for a minimum of one year.
- (4) Review materials to be presented at convened SRS meetings.
- (5) Have three-year appointments.

(6) Also have a three-year appointment on the Institutional Review Entity (IRE).

(5) ALTERNATE VOTING MEMBERS

(1) Serve in lieu of voting members.

(2) Have the same qualifications as the “mandatory” or “other” voting member as listed above.

(3) Have three-year appointments.

(4) Also have a three-year appointment on the Institutional Review Entity (IRE).

(6) *Ex-officio* MEMBERS

(1) *Ex-officio* members include the RSC, who serves as Secretary (voting), the Administrative Officer/Research or other non-voting representative from the R&D office (non-voting), a liaison member of the local R&D Committee (voting), and an employee union safety designee.

(2) Review materials to be presented at convened SRS meetings.

(3) Serve on the Institutional Review Entity (IRE).

(7) SRS Chair

(1) Must be a VA-associated Principal Investigator for a minimum of one year.

(2) Attends at least 50% of the convened SRS meetings.

(3) Serves as a voting member on Case Western Reserve University’s Institutional Biosafety Committee. He/she must be present when non-exempt synthetic and recombinant nucleic acid studies conducted at or are associated with the Louis Stokes Cleveland Department of Veterans Affairs Medical Center.

(4) Reviews materials to be presented at convened SRS meetings.

(5) Has a one-year appointment.

(6) Also serves as Chair of the Institutional Review Entity (IRE).

(8) SRS Alternate Chair

(1) Must be a VA-associated Principal Investigator for a minimum of one year.

(2) Attends in lieu of the SRS Chair.

(3) Serves as a voting member on Case Western Reserve University's Institutional Biosafety Committee. He/she must be present in lieu of the SRS Chair when non-exempt synthetic and recombinant nucleic acid studies conducted at or are associated with the Louis Stokes Cleveland Department of Veterans Affairs Medical Center.

(4) Reviews materials to be presented at convened SRS meetings.

(5) Has a one-year appointment.

(6) Also serves as Alternate Chair of the Institutional Review Entity (IRE).

5. REFERENCES: Medical Center Policy 151-007, Subcommittee on Research Safety.

6. RESCISSIONS: Medical Research Policy 151-026 dated May 4, 2017. The rescission date of this Subcommittee on Research Safety Policy is July 12, 2023.

7. FOLLOW UP: RSC/CHO