VA NORTHEAST OHIO HEALTHCARE SYSTEM

Louis Stokes Cleveland VAMC Medical Research Service Subcommittee on Research Safety Policy

Effective Date: JANUARY 25, 2023 Policy Title: SUBCOMMITTEE ON RESEARCH SAFETY MEMBERSHIP Policy Number: SRS026 Policy Version:.04			
		Author:	
		Name:	John M. Schaffer, B.A
Title:	Research Safety Coordinator		
Departmen	t: Medical Research Service		
$\overline{\mathbf{Jo}}$	hn M. Schaffer, B.A.		
Reviewed	By:		
Cł	nair/Subcommittee on Research Safety:		
Kı	risztina M. Papp-Wallace, Ph.D.		
Approved	By:		
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As	sociate Chief of Staff/Research		
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Ne	al S. Peachey, Ph.D.		

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Effective Date: JANUARY 25, 2023

SOP Title: SUBCOMMITTEE ON RESEARCH SAFETY MEMBERSHIP

SOP Number: SRS--026

SOP Version: .04

- 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 SRS Committee Members when an opening on the SRS exists.
- (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 <u>Subcommittee on Research Safety Membership</u> to ensure that candidates and/or re-appointees meet the qualifications outlined in Section 5, <u>Procedure</u>, 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 reappointee 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 Policy <u>Subcommittee on Research Safety Membership</u> to ensure that a candidate Page 2 of 5

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) Vote to approve <u>or</u> disapprove a candidate or re-appointee at a convened SRS meeting when quorum is met.
- (6) Two SRS voting members (with knowledge/understanding of work involving recombinant DNA and synthetic nucleic acids) must serve on Case Western Reserve University's Institutional Biosafety Committee (IBC)*. Only one member needs to be in attendance when non-exempt synthetic and recombinant nucleic acid studies conducted at/associated with the Louis Stokes Cleveland Department of Veterans Affairs Medical Center are on an IBC agenda. Attendance at monthly IBC meetings needs to be coordinated between these two members.
- *The SRS nominates potential candidates to serve as voting members on the IBC. The IBC makes the determination as to who will be approved to serve.

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 <u>Subcommittee on Research Safety Membership</u> 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).

c. 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).

d. Ex-officio MEMBERS

- (1) *Ex-officio* members include the RSC, who serves as Secretary (voting), an employee union safety designee, a representative from the Facility Safety Office, a liaison voting or non-voting member of the facility R&D Committee who will serve as a non-voting member of the SRS, and may include a representative from Personnel Health Service.
- (2) Have three-year appointments.
- (3) Review materials to be presented at convened SRS meetings.
- (4) Serve on the Institutional Review Entity (IRE).

e. 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) Reviews materials to be presented at convened SRS meetings.
- (4) Has a one-year appointment.
- (5) Also serves as Chair of the Institutional Review Entity (IRE).

- f. 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) Reviews materials to be presented at convened SRS meetings.
 - (4) Has a one-year appointment.
 - (5) Also serves as Alternate Chair of the Institutional Review Entity (IRE).
- 5. REFERENCES: Medical Center Policy 151-007, <u>Subcommittee on Research Safety</u>.
- 6. RESCISSIONS: Medical Research Policy SRS-026. The rescission date of this Subcommittee on Research Safety and Security Policy is January 24, 2028.
- 7. FOLLOW UP: RSC/CHO