

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Wednesday, June 3, 2026  
**Time:** 8:00 am Pacific Time  
**Location:** Zoom Teleconference  
**Institution:** Sharp HealthCare, San Diego, CA  
**Principal Investigator:** Brian Jaski, MD  
**Protocol:** Sardocor Corp., SRD-001-1001  
**NCT Number:** NCT04703842  
**Meeting Type:** Continuing Review of Protocol and Site  
**Title:** A Phase 1b/2 Trial of the Safety and Efficacy of SRD-001 (AAV1/SERCA2a) in Subjects with Heart Failure with Reduced Ejection Fraction

### 1. Call to order:

The Meeting was called to order at 8:00 am Pacific Time.

### 2. Introductions and orientation:

Introductions were made and the Chair oriented members to the meeting procedures.

### 3. Declaration of quorum:

Four voting members were present, including one local member unaffiliated with the institution. Also present were five Institutional Representatives and IBC Services staff. The Chair declared that a quorum was present.

### 4. Conflict of Interest:

The Chair requested that voting members report any conflict of interest regarding this meeting. No conflicts of interest were reported.

### 5. Public posting:

An Institutional Representative confirmed that notice of the meeting was publicly posted. No public comments were received by the site or the Committee regarding this review.

### 6. Approval of previous meeting minutes:

Minutes Approved - YES: 4                      NO: 0                      ABSTAIN: 0

### 7. Review of proposed research:

The Chair provided an overview of the protocol and status of the study.

The Chair noted changes since the last review.

### 8. Determination for biosafety level and period of IBC oversight:

The Committee previously determined that **BSL-1 containment facilities and practices plus Standard Precautions** are required for SRD-001 since it consists of an AAV vector administered by infusion in a clinical setting. The Committee reaffirmed this determination.

The Committee previously determined that IBC oversight will continue for **3 months after the last subject's last dose of SRD-001 locally**, provided all other biosafety criteria for study closure are also met. The Committee reaffirmed this determination.

### 9. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 4                      NO: 0                      ABSTAIN: 0

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### **10. Review of proposed facilities and practices:**

The Chair provided an overview of the arrangement for the facilities and practices.

#### **Points of Discussion:**

1. The Committee recommended that Biosafety SOP Section 3.4.1 be revised to include absorbent material in the Ziploc-style bag for internal transport.
2. An Institutional Representative confirmed that the entrance to the preparation room is labeled with biohazard signage and that Institutional policy prohibits the labeling of the Biological Safety Cabinet (BSC) itself.
3. The Committee noted the following: Under the California Medical Waste Management Act, biohazardous waste must be placed in biohazard bags and labeled in accordance with Health and Safety Code §117630 and then placed in rigid containers. Certain secondary containers (e.g., for chemotherapy or pathology/biohazardous waste) must be labeled on the lid and sides so as to be visible from any lateral direction. Containers used for storage or transport must be leak-resistant and maintain closure to prevent release of contents.
4. The Committee recommended that an updated photo of the biohazardous waste container in the dosing room be submitted to IBC Services.
5. An Institutional Representative confirmed that all biohazardous waste is transported to the Biohazardous Waste Storage Area on a wheeled cart.
6. An Institutional Representative confirmed that the location of Room 221 (biohazardous waste storage) is in another area of the Institution. The Committee recommended that a Site Map of this area be provided to IBC Services; an Institutional Representative agreed to check with upper management to see if they are able to provide a Site Map of this area.
7. The Committee noted a discrepancy in the BSC Certification and an Institutional Representative noted that this BSC is located in the preparation room. The Committee recommended that the Institution follow up to confirm that the BSC noted in the Certification is the BSC that is noted in the Pharmacy Site Map.
8. The Committee noted that one of the IATA/DOT Shipping Training certificates appeared invalid (two other valid certificates are available) suggesting the incorrect page may have been uploaded. The Committee recommended that a valid record of training completion be provided to IBC Services.
9. An Institutional Representative confirmed that all phone numbers on the biohazard sign are monitored 24/7.

### **11. Site requirements:**

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representatives.

### **12. Vote on the Site:**

The Committee voted for the following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 4

NO: 0

ABSTAIN: 0

### **13. Advice to the Institution:** None.

**14. Meeting adjourned:** The meeting was adjourned at 8:22 am Pacific Time.

**15. Post-meeting notes:** None.

### **Documents reviewed:**

Agenda

Protocol, Version 5.1, Amendment 4.1, dated 05-09-2023

Investigator's Brochure, Version 4, dated 08-10-2022

Pharmacy Manual, Version 6.1, dated 09-25-2024

Research Modification Evaluation, Pharmacy Manual, Version 6.1

Biological Risk Assessment and Summary, updated 12-23-2025

Site Map, Infusion Center, dated 05-31-2023

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Site Map, Sharp Central Pharmacy, dated 06-26-2023  
Site Inspection Checklist, expires 04-30-2027, updated 11-05-2025  
Photos, dated 05-18-2026  
Biohazard Sign, dated 05-18-2026  
Biological Safety Cabinet Certification, expires 07-31-2026  
SOP, Biosafety for SRD-001, dated 05-09-2024  
Training, Shipping Certifications, expire 2026  
CRRF, dated 03-02-2026  
Prior Meeting Minutes, Continuing, dated 06-26-2025