INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Wednesday, October 29, 2025

Time: 11:00 am Eastern Time
Location: Zoom Teleconference
Institution: InSoma Bio, Durham, NC
Principal Investigator: Stefan Roberts, PhD
Project: InSoma Bio, INSOMA-001

Meeting Type: Continuing Review of Project and Site

Title: Production, use, and analysis of recombinant proteins

1. Call to order:

The Meeting was called to order at 11:01 am Eastern 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 two local members unaffiliated with the institution. Also present were two Institutional Representatives, the Principal Investigator, 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 project.

The Chair provided an overview of 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** are required for all work with laboratory strains of *Escherichia coli*. The Committee reaffirmed this determination.

The Committee previously determined that **IBC oversight will continue as long as active research is ongoing**. The Committee reaffirmed this determination.

9. Vote on project:

The Committee voted for following determination on the Project:

	X	APPROVED
		CONDITIONALLY APPROVED
Ī		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. An Institutional Representative noted that the work is migrating to different spaces within the facility, but the focus of the research has not changed since it was last approved at BSL-1.
- 2. The Committee recommended that the inSoma Spill Response, ECP, and Clean Up SOP be revised to indicate that the first step is spill containment and the PI is contacted after that.
- 3. The Committee recommended that Site Inspection Checklist (#5) be revised to replace "primary care physician" with an appropriate occupational health & safety provider.
- 4. An Institutional Representative confirmed that all biohazardous waste, whether autoclaved or not, is ultimately collected by a licensed biohazardous waste hauler.
- 5. The Committee recommended that the Autoclave addendum be revised to indicate that the autoclave is validated by building management.
- 6. The Committee noted a sharps container on the windowsill as shown in a site photo. An Institutional Representative stated that it is only placed there when not in use and moved to the benchtop when needed.
- 7. The Committee noted different versions of biohazard signs on doors, specifically that some have red and some do not. The Committee recommended that biohazard signs be larger with the biohazard symbols printed in red if possible.
- 8. The Committee recommended that all biohazardous waste containers be lidded when not in use.

11. Site responsibilities:

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

12. Vote on the site:

The Committee voted for following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 4

NO: 0

ABSTAIN: 0

13. Advice to Institution: None.

14. Meeting adjourned: The meeting was adjourned at 11:31 am Eastern Time.