

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Monday, December 15, 2025
Time: 11:00 am Pacific Time
Location: Zoom Teleconference
Institution: Immusoft, Seattle, WA
Principal Investigator: Andres (Glen) Grandea III, PhD
Project: Immusoft Corporation, Immu-001 (bench)
Meeting Type: Continuing Review of Project and Site
Title: Engineering of human B cells using the Sleeping Beauty Transposon System

1. Call to order:

The Meeting was called to order at 11:00 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 two local members unaffiliated with the institution. Also present were 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:

The Principal Investigator 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.

Points of Discussion:

1. The Principal Investigator stated that modified B cells are currently being tested in a Phase 1 clinical trial being overseen by other IBCs, with positive preliminary results.
2. The Principal Investigator stated that all work overseen by this IBC is pre-clinical in nature.
3. The Principal Investigator stated that lentiviral vectors are not currently used in the research. The Committee emphasized that if work with lentiviral vectors commences, vectors and vector-transduced cells must only be handled within a Biological Safety Cabinet (BSC), all relevant site documents must be revised accordingly, and IBC Services must be notified.
4. The Principal Investigator stated that infectious agents are not currently used in the research.

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 all recombinant DNA outside of cells and in K12-derived *E. coli*. The Committee reaffirmed this determination.

The Committee determined that **BSL-2 containment facilities and practices** are required for all work with non-transduced cells.

The Committee determined that **BSL-2 containment facilities and practices with enhanced precautions** are required for all work with lentiviral vectors and lentiviral vector transduced cells. Enhanced Precautions include: use of a BSC, full PPE for mucosal protection, and sharps avoidance.

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The Committee previously determined that **IBC oversight will continue as long as active research on this project continues**. The Committee reaffirmed this determination.

9. Vote on project:

The Committee voted for following determination on the Project:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 4

NO: 0

ABSTAIN: 0

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 Principal Investigator stated that live cells are isolated and sorted using cell sorters which are self-contained in closed systems, located outside of the [REDACTED]
2. The Principal Investigator stated that all cell culture work is done inside a BSC.
3. The Committee recommended that the Laboratory Safety Manual be revised to accurately reflect the occupational health provider.
4. The Principal Investigator clarified the difference between the [REDACTED] and the [REDACTED]
5. The Principal Investigator confirmed that the research involves human blood or other potential infectious materials. The Committee recommended that Site Inspection Checklist (#3) be revised accordingly.
6. The Principal Investigator stated that needles, pipets, and automated cell counters are used. The Committee determined that none of these are reusable sharps and recommended that Site Inspection Checklist (#15) be revised accordingly.
7. The Principal Investigator stated that 10% bleach solution followed by ethanol is used for spill clean-up and to decontaminate work surfaces.
8. The Committee recommended that handwashing sinks be more clearly indicated on the site map.
9. The Principal Investigator stated that study staff use hand sanitizer prior to leaving the [REDACTED] and then wash hands their hands at the closest sink.
10. The Committee recommended that photos, which more clearly show the work space and equipment used, be provided to IBC Services.
11. The Principal Investigator stated that biohazardous waste is collected from a designated staging area in the [REDACTED]. The Committee recommended that this area be clearly indicated on the site map.
12. The Committee recommended that the BSCs be labelled with biohazard symbols.
13. The Committee noted that a study staff member is overdue for annual BBP training and recommended that this training be completed.

11. Site responsibilities:

The Chair reviewed communication requirements for maintaining IBC approval with 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.

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14. Meeting adjourned: The meeting was adjourned at 11:32 am Pacific Time.