TEXAS STATE UNIVERSITY.
Division of Research

Institutional Biosafety Committee
Meeting Minutes

DATE: September 17, 2026
TIME: 10:00 AM
LOCATION: Teams:

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1. Call to Order/ Member Introductions

The meeting for the Texas State University Institutional Biosafety Committee (IBC) - was called to order by the Chair at 10:00 PM. This meeting was open to the public.

MEETING ATTENDANCE:

Voting members present: 8 (BSO alternate vote will not count)
Voting members required for quorum: 5

Voting IBC Members Present:

☒ Dr. Hong-Gu Kang, IBC Chair
☒Elsie Romano, BSO
☒Smitha Rayadurg, BSO Alternate
☒Dr. Michelle Lane
☒Dr. Sean Kerwin
☒Dr. Matthew McAllister
☒Dr. Cesar Rosales-Nieto
☐Brigid Lednicky, Community Member
☒Monty Gomez, Community Member

Ex Officios:

☒Monica Gonzales ☒Sean Rubino ☐Dr. Michael Blanda

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Guests Present:
Wendy McCoy, Director EHSREM
Chad Thomas, Supervisor EHSREM
Dr. Jason Ramage, AVP Research Integrity

2. New Business/Announcements

- USG Policy for Stopping High Risk Life Sciences Research

The United States Government (USG) Policy for Stopping High-Risk Life Sciences Research (issued July 20, 2026 pursuant to Executive Order 14292) represents a fundamental shift in biological research oversight. Instead of focusing on "risk mitigation," this policy shifts to the outright prohibition of federal funding for designated high-risk life sciences activities.

Key points the Institutional Biosafety Committee (IBC) needs to know:

1. Categories of Restricted Research
The policy identifies two primary categories of research posing the highest national and public health risk:
• Dangerous Gain-of-Function (DGOF) Research: Research involving a biological agent that seeks, achieves, or carries a substantial risk of achieving outcomes that make the agent more dangerous. This includes enhancing harm, undermining vaccines or immunity, conferring resistance to therapeutics, increasing transmissibility, altering host ranges, or reconstituting extinct/eradicated agents (including creating "mirror organisms"). Federal funding for DGOF research is categorically barred.
• International Research of Concern (IROC): Research conducted in or by "countries of concern," with "entities of concern," or conducted outside the U.S. in regions lacking adequate biosafety oversight. Federal funding is prohibited for certain IROC.

2. Comprehensive Scope (Regardless of Funding)
• The review scope applies to all proposed and ongoing life sciences research at the institution, regardless of the funding source.
• Institutions must implement monitoring mechanisms to capture and track non-federally funded DGOF or potential DGOF research, which must be reported annually to their primary federal life sciences funding agency.

3. Institutional Review Infrastructure
• Establishment of an IRE: Covered institutions must establish an Institutional Review Entity (IRE), designate an institutional contact, and implement formal

oversight procedures. In practice, this responsibility often falls directly upon or closely aligns with the IBC.

• Mandatory Attestations: Principal Investigators (PIs) and institutions must submit written attestations certifying that proposals have been evaluated against DGOF and IROC criteria before funding or work can proceed.
• Annual Evaluations: The IRE must conduct at least annual evaluations of active projects against the new criteria.

4. Pathways for "Potential" DGOF
• Research flagged as having "potential" DGOF characteristics is not automatically banned, but it cannot proceed under standard institutional authorization.
• It must undergo a risk-benefit assessment, have an approved mitigation plan, and pass evaluation by a single, public-facing, federal Independent Third-Party Review Body before any federal funding can be cleared.

5. Immediate Stop-Work Mandate
• If ongoing research is discovered to potentially meet the DGOF definition, the policy mandates an immediate stop-work order.
• The institution must notify the respective federal funding agency within 24 hours.

Timeline for the IBC
Federal agencies (like HHS and NIH) have 120 days from the July 2026 issuance to release final institutional implementation guidance. Full institutional compliance across the research enterprise is expected by January 16, 2027

TXST will incorporate this policy into our TXST IBC policy UPPS 04.05.17 with IBC member feedback. Public comments on the USG Policy can be submitted to Office of Science Policy by October 19, 2026. Our current Chair Dr, Hong-Gu. Kang will serve as chair of the IRE when required. All potential gain-of-function projects have been reviewed by a subcommittee of Dr. Kang and Dr. Kerwin. TXST currently has no gain-of-function protocols, and moving forward, the subcommittee will add new IBC members, Dr. Lane and Dr. Rayadurg, to review potential gain-of-function and dangerous gain-of-function protocols submitted for review. Subcommittee members were identified based on their expertise. Any projects involving “countries of concern” or “entities of concern” are also reviewed by the Research Integrity and Compliance export control officer, Sean Rubino. Continuing the collaborative oversight of committees and appropriate departments.

Motion/Approval: Not required (discussion)

- Policy Committee

  Dr. Ramage, as AVP of Research Integrity and Compliance, is reassessing all committees to ensure diverse representation at Texas State University. Current IBC members were asked if there was a certain department or type of protocols and the board needs more representation. Currently, based on situational awareness of all IBC activity and protocols, Dr. Kang expressed that, in his opinion, there was sufficient representation, considering the addition of new members to the roster in September with expertise in recombinant DNA work and animals. Dr. Kerwin suggested seeing a list of departments that submit IBC protocols for an informed decision. Monica agreed these numbers can be provided for the committee to make an informed decision.

  Motion: Tabled for next scheduled IBC meeting
  Votes: 8 Favor; 0 Against; 0 Abstain; 0 Recuse

3. Conflict of Interest Disclosures/Confidential

   Members were reminded of their responsibility to disclose conflicts of interest and recuse themselves from related discussion and voting. Because meetings are open to the public, members were also advised to exercise discretion when discussing researchers and potentially sensitive information.

4. Approval of prior minutes

   The minutes from the August 18, 2026 meeting were distributed to the committee for review prior to the session. Additional time was allocated during the meeting for members to review the document. Dr. Hong Gu Kang emailed minor edits, which Elsie Romano noted during the meeting. The minutes were approved subject to these amendments.

   Motion: approved with edits
   Votes: 5 Favor; 0 Against; 2 Abstain; 0 Recuse

5. Protocol Requiring Committee Review/Approval

   No protocols required review or approval during this meeting.

6. Administrative Activity Report from 08/17/26 to 9/17/26

The Biosafety Program Report was presented for committee review. Since the previous Texas State University Institutional Biosafety Committee (IBC) meeting on August 18, 2026, the Office of Research Integrity and Compliance received three submissions for review. These were processed by the Biosafety Program Staff and subsequently approved by the IBC Chair or delegated committee member on behalf of the committee. Of these submissions, one did not require IBC oversight.

These administrative and expedited actions may include:
• Simple amendments (e.g., personnel or room changes)
• Renewal applications with no changes to risk levels for non-recombinant or exempt studies
• Administrative actions (e.g., verification of no IBC oversight or close requests)
• Annual reviews

7. *Inspection/Safety Program Updates*

Environmental Health, Safety, Risk and Emergency Management (EHSREM) identified that two laboratories failed to meet the negative air pressure requirements needed to maintain Biosafety Level 2 (BSL-2) containment due to recent renovations. While both facilities have approved BSL-2 protocols, the following corrective measures and statuses were verified by Monica and the BSO:

• First Impacted Laboratory: The Principal Investigator (PI) confirmed that no BSL-2 work has been conducted in this space, and all such work is suspended until the ventilation issue is resolved.
• Second Impacted Laboratory: The PI has not yet initiated any BSL-2 research and will delay the start of all work until compliance is achieved.

8. *Other Business/Public Comments*

There was no other business brought before the committee, and no public comments were received.

9. *Adjournment*

The Institutional Biosafety Committee (IBC) meeting was adjourned at 2:06 AM. The next scheduled meeting is set for October 20, 2026.