

INSTITUTIONAL BIOSAFETY COMMITTEE

Tuesday, 06/17/2025 12:06 PM MSBII 5A116

Chairperson

Mingtao Zeng, Ph.D.

Board Members

Anthony W Baird, DSc Jeana E. Barrow, DVM Huanyu Dou, M.D. Pallavi Dubey, Ph.D. Ivan E Flores, BS Daniel Gonzales, BA Sehrish Javaid, BDS, MS, Ph.D

Administrative Staff

Amanda Ortiz Myrna Arvizo

MEMBERS PRESENT

Anthony W Baird, DSc, Jeana E. Barrow, DVM, Huanyu Dou, MD, Pallavi Dubey, PhD, Ivan E Flores, BS, Daniel Paul Gonzales, BMS, Mingtao Zeng, PhD

MEMBERS ABSENT

Sehrish Javaid, BDS, MS, PhD

STAFF PRESENT

Myrna Arvizo, BMS, CIP, CHRC, Barbara S Castellanos, M.S., Amanda Ortiz

GUESTS PRESENT

N/A

CALL TO ORDER

Mingtao Zeng, PhD Chair called the meeting to order at 12:06 p.m. Quorum is 5 members. 7 members are present at the call to order, including scientific, non-scientific and non-affiliated members. 7 members present at conclusion.

All proceedings and discussion in the upcoming meeting are confidential and should not be discussed outside of the meeting. Additionally, any member who has a conflict of interest that would preclude making an objective determination about a study should recuse him/herself from voting on the study.

A draft of the meeting minutes from 05/20/2025 was distributed for review on 06/16/2025. There were no controversial entries or objections. A motion to approve the meeting minutes as written was made by HD and

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seconded by AB. The committee voted unanimously to approve the minutes.

The meeting was adjourned at 1:10 p.m.

M	IS	CEL	.LAI	NEC	DUS

N/A

3-YEAR RENEWALS

N/A

AMENDMENTS

N/A

INITIAL REVIEWS

IBC# 25006 Full Renewal Expiration Date: 07/31/2028

Narges Khanjani, PhD/TTUHSC El Paso - SOM - Medical Education

Biosafety Level: BSL 2

ADMINISTRATIVE COMMENT:

Comment:

The PI has responded to the concerns of the committee. The concerns were: 1. In the Study Application: 5.1 - Please clarify whether the umbilical cord will be collected for this study. If so, who will collect the samples, where will the samples be collected, and where will they be stored? 2. In the Study Application: 5.1 - Please provide additional information regarding Dr. Padilla's role. Is she serving as the pathologist for this protocol? 3. In the Study Application: 5.1 - Who will be responsible for collecting the placenta samples? 4. In the Study Application: 5.3 - What location(s) will the placenta be collected? 5. In the Study Application: 7.3 - Indicate whether any body fluids will be used? 6. In the Study Application: 7.3 - Please clarify the phrase "mothers after labour" used as the source of placental material.

MEMBER COMMENTS:

Comment:

The clarifications requested by the IBC do not involve Safety. As commented previously, Safety has no concerns with this protocol.

Comment:

In this study a sample, the size of a small ice-cube (approximately 1 inch cubed and weighing approximately 1 gram), will be taken approximately 4 CMs from the insertion site on the maternal side of the placenta in the delivery room or pathology department of the UMC (within 24 hours of the delivery prior to the placenta being discarded). The sample will be taken by a pathologist (Dr. Padilla) or an OBGYN specialist (Dr. Meserow) or a medical student (Ms. Thotakura) under the supervision of one of these two physicians. The umbilical cord will not be collected. The sample will be placed in test tubes and then into plastic bags to be transferred to the lab at MEB 4100 where it will be flash frozen using nitrogen until transferred to the lab in New Mexico. No bodyfluids other than liquid contained in the placenta will be used in the study. Samples will be stored in -80 degrees Centigrade until 50 samples have been collected and then shipped under a material transfer agreement in a triple-layered containment per institution and federal transport guidelines regarding cryogenic tubes, sealed biohazard bags and an insulated Styrofoam-lined cooler with dry ice. An SDS will accompany the shipment. The samples will be transported off-campus via FedEx overnight priority on a Monday morning to the University of New Mexico laboratory in Albuquerque. FedEx, a certified carrier, will handle all off-campus transport to ensure compliance with DOT/IATA regulations for dry ice and biological materials. Chain-ofcustody documentation will be maintained from collection through delivery at the receiving lab. After the samples reach the University of New Mexico laboratory in Albuquerque, microplastic concentrations will be measured using Pyrolysis-Gas Chromatography/Mass Spectrometry (Py-GC/MS), and heavy metal levels will be analyzed using Inductively Coupled Plasma Mass Spectrometry (ICP-MS).

All biologic sample handling and analysis will follow standardized protocols to minimize contamination.

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RECOMMENDATIONS: Approve **SUBMISSION OUTCOME**: Approved

IBC# 25006 Full Renewal Expiration Date:

Narges Khanjani, PhD/TTUHSC El Paso - SOM - Medical Education

Biosafety Level: BSL 2

ADMINISTRATIVE COMMENT:

Comment:

The PI has responded to the stipulations. In iRIS, navigate to the Submission Components tab and open the Revisions folder under the IBC Study Application. Then, click on Compare Items to view the changes made by the PI. Additions will be highlighted in green, and deletions will appear in pink.

MEMBER COMMENTS:

Comment:

With the revisions addressing requests for details in sections 7 and 9, the proposed study is recommended for approval.

Comment:

Does the IBC need to know who will be collecting the placenta samples? These are comments from the IRB:Protocol indicates: It will be placed in cryogenic-safe experimental tubes. - are these tubes being provided by TTUHSC EP? The sample will be flash frozen using liquid nitrogen. - where will the specimens be flash frozen? Will this take place at a TTUHSC EP lab or UMC EP? If UMC EP, where? Samples will be stored in 80°C freezers until all 50 samples are ready for transportation - where is the freezer located?

RECOMMENDATIONS: Additional Information Required

STIPULATIONS: 1. **In the Study Application:** 5.1 - Please clarify whether the umbilical cord will be collected for this study. If so, who will collect the samples, where will the samples be collected, and where will they be stored?

- 2. **In the Study Application:** 5.1 Please provide additional information regarding Dr. Padilla's role. Is she serving as the pathologist for this protocol?
- 3. In the Study Application: 5.1 Who will be responsible for collecting the placenta samples?
- 4. In the Study Application: 5.3 What location(s) will the placenta be collected?
- 5. In the Study Application: 7.3 Indicate whether any body fluids will be used?
- 6. **In the Study Application:** 7.3 Please clarify the phrase "mothers after labour" used as the source of placental material.

MOTION AND VOTE: The TTUHSC EP Institutional Biosafety Committee (IBC) reviewed the initial application at their full board meeting and determined that additional information or modifications are required. Total Members Voting: **7** [For: **7** Absent: **0** Against: **0** Conflict of Interest: **0** Not Present: **0** Abstained: **0**]

SUBMISSION OUTCOME: Additional Information Required

IBC# 25006 Full Renewal Expiration Date:

Narges Khanjani, PhD/TTUHSC El Paso - SOM - Medical Education

Biosafety Level: BSL 2

ADMINISTRATIVE COMMENT:

Comment: 1.

This is an Initial Application. The PI is requesting

Space: MEB 4100 Chemicals: N/A

Biological Agents: Human Tissue

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Biosafety Level: BSL-2

Transport and hazardous shipper training is required.

This protocol does not involve recombinant or synthetic nucleic acid molecules.

In section 7.3 the PI should provide the details of the procedures used with the type of material. Unlike the IRB, the IBC does not require separate documentation. All information should be added to the application. In section 9.5 and 9.6 the PI should provide the details of the procedures used with the type of material. Unlike

the IRB, the IBC does not require separate documentation. All information should be added to the application.

MEMBER COMMENTS:

Comment:

This protocol shows no hazardous chemicals for use, storage or spill control. There is also no infections biological material. MEB rm4100, also called the LEMM, is a very clean well organized laboratory. Fume hoods, BSCs, eye washes, emergency showers, and all other safety measures are 100% in this location. Once required shipping and transport training is done, Safety Services does not have any concerns with this submission.

Comment:

Using MEB 4100, BSL-2 seems appropriate. However, I do not find the more specific process details asked for in 7.3, 9.5, and 9.6. I also do not see completion or clearance for shipping and handling training provided by Safety.

RECOMMENDATIONS: Additional Information Required

STIPULATIONS: 1. In section 7.3 the PI should provide the details of the procedures used with the type of material. Unlike the IRB, the IBC does not require separate documentation. All information should be added to the application.

2. In section 9.5 and 9.6 the PI should provide the details of the procedures used with the type of material. Unlike the IRB, the IBC does not require separate documentation. All information should be added to the application.

SUBMISSION OUTCOME: Additional Information Required

IBC# 25005 Full Renewal Expiration Date: 07/31/2028

Julianna Santos/TTUHSC El Paso - SOD - School of Dentistry

Biosafety Level: BSL 1

ADMINISTRATIVE COMMENT:

<u>Comment</u>: 1. The PI has responded to the concerns of the committee. Please advise if the PI requires IBC approval. The concerns were:1. In the Study Application: 5.1 - Please elaborate on your specific role and responsibilities as Principal Investigator in the conduct and oversight of this project. Please also clarify whether you will already have access to the slides per your role as an instructor in the anatomy lab. 2. In the Study Application: 5.1 - It indicates that the research will correlate specimens with diagnostic information from the death certificate and demographical information. Please clarify how/where this information is available and/or provided for research purposes. Also, is any of the data, images, and demographic/diagnostic information identifiable or fall under HIPAA regulations? 3. In the Study Application: 5.3 - Please specify the physical location(s) where the cadaver images will be reviewed, stored, or analyzed. Include any relevant room or building information. 4. In the Study Application: 7.3 - Please provide the information for "Source of material"-such as the Department of Anatomy, and "Use of material" --such as imaging and picturing the brain specimen for teaching. Same as Section 7.6 5. In the Study Application: 9.3 - please explain how the information (e.g., photographs and any related data) will be used for research purposes.

MEMBER COMMENTS:

Comment:

I have no further concern.

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Comment:

Upon further clarification, images collected in the gross anatomy lab will be used for the research in this license. Research is NOT being done in the gross anatomy lab. Safety Services and Biological Safety Officer do not have any concerns with this research and/or protocol.

RECOMMENDATIONS: Approve **SUBMISSION OUTCOME**: Approved

IBC# 25005 Full Renewal Expiration Date:

Julianna Santos/TTUHSC El Paso - SOD - School of Dentistry

Biosafety Level: BSL 1

ADMINISTRATIVE COMMENT:

Comment:

This is an Initial Application. The PI is requesting

Space: MEB Gross Anatomy Lab

Chemicals: N/A

Biological Agents: Human Tissue, Human Brain

Biosafety Level: BSL-1

Transport and hazardous shipper training are not required.

The PI is pending LSE training, however it was assigned on 6/10/25.

This protocol does not involve recombinant or synthetic nucleic acid molecules.

MEMBER COMMENTS:

Comment:

When reviewing this submission, I do not have any safety concerns for what the PI would like to do in this lab. Upon reaching out to the Gross Anatomy lab, the manager and Director advised that no PI is allowed to use this location for research. Below is a line from an email from gross anatomy lab director: "Our gross anatomy labs are rated for BSL1 work only and we are not approved for work requiring an IBC approval. The labs should not be listed in any IBC applications". And added that she would talk to the PI about removing this location from the IBC application.

Comment:

The application mentions that there is a research project involved. If they are unable to use the lab for research, how will this be accomplished? The procedure seems to only involve taking pictures of existing specimens, but it is not clear how this will be done. Are these specimens already available for pictures or do they need to be extracted? The abstract indicates that they will later correlate normal or variations specimens with the diagnostics from the death certificate and also with the demographical information. Where is the death certificate and demographic information coming from? There is no IRB protocol associated if this includes identifiers. Only the PI is listed on the application. Will she be the only one involved?

RECOMMENDATIONS: Additional Information Required

STIPULATIONS: 1. In the Study Application: 5.1-Please elaborate on your specific role and responsibilities as Principal Investigator in the conduct and oversight of this project. Please also clarify whether you will already have access to the slides per your role as an instructor in the anatomy lab.

- 2. **In the Study Application**: 5.1-It indicates that the research will correlate specimens with diagnostic information from the death certificate and demographical information. Please clarify how/where this information is available and/or provided for research purposes. Also, is any of the data, images, and demographic/diagnostic information identifiable or fall under HIPAA regulations?
- 3. **In the Study Application:** 5.3-Please specify the physical location(s) where the cadaver images will be reviewed, stored, or analyzed. Include any relevant room or building information.

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- 4. **In the Study Application:** 7.3/7.6-Please provide the information for "Source of material"--such as the Department of Anatomy, and "Use of material" --such as imaging and picturing the brain specimen for teaching.
- 5. **In the Study Application:** 9.3-Please explain how the information (e.g., photographs and any related data) will be used for research purposes.

MOTION AND VOTE: The TTUHSC EP Institutional Biosafety Committee (IBC) reviewed the initial application at their full board meeting and determined that additional information or modifications are required. Total Members Voting: **7** [For: **7** Absent: **0** Against: **0** Conflict of Interest: **0** Not Present: **0** Abstained: **0**]

SUBMISSION OUTCOME: Additional Information Required

EXPEDITED REVIEW

N/A

ADMINISTRATIVE-ANNUAL STATUS REPORTS

IBC# 20003 Full Renewal Expiration Date: 06/30/2026

Sireesha Reddy, MD/TTUHSC El Paso - SOM - Obstetrics and Gynecology-Texas Tech Medical Center

Biosafety Level: BSL 2

ADMINISTRATIVE COMMENT:

Comment:

This is an Annual Status Report. COI, FD, and LSE are complete for the PI and staff. The study does include shipper and on-campus training. This training is complete for those listed in section 5.5 and 5.6. This is a BSL2 study. This protocol does not involve recombinant or synthetic nucleic acid molecules.

RECOMMENDATIONS: Acknowledged

SUBMISSION OUTCOME: Administratively Acknowledged

ADMINISTRATIVE-AMENDMENTS

IBC# 25002 Full Renewal Expiration Date: 12/31/2027

Murali Bagalur Muniraju, Ph.D./TTUHSC El Paso - SOM - Molecular and Translational Medicine

Biosafety Level: BSL 2

ADMINISTRATIVE COMMENT:

Comment:

Personnel change to add Janet Olivas. COI, FD, and LSE are complete. This protocol includes synthetic nucleotides and plasmid vectors.

RECOMMENDATIONS: Acknowledged

SUBMISSION OUTCOME: Administratively Acknowledged

IBC# 22007 Full Renewal Expiration Date: 07/31/2025

Pallavi Dubey, PhD/TTUHSC El Paso - SOM - Obstetrics and Gynecology-Texas Tech Medical Center

Biosafety Level: BSL 2

ADMINISTRATIVE COMMENT:

Personnel change to add Richa Patel. COI, FD, and LSE are complete. The PI is also requesting to remove Dwija Dammanna. This protocol does not involve recombinant or synthetic nucleic acid molecules.

RECOMMENDATIONS: Acknowledged

SUBMISSION OUTCOME: Administratively Acknowledged

IBC# 18014 Full Renewal Expiration Date: 07/31/2027

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Benjamin Carcamo, MD/TTUHSC El Paso - SOM - Pediatrics-Texas Tech Medical Center

Biosafety Level: BSL 2

ADMINISTRATIVE COMMENT:

MEMBER COMMENTS:

<u>Comment</u>: 1. Personnel change to remove Carla Diaz. Christina, Paulina, Diluma, and Leann who are already listed on the license have been added to section 5.5 as hazardous shippers. Shipper training is current. This protocol does not involve recombinant or synthetic nucleic acid molecules.

Comment

RECOMMENDATIONS: Acknowledged

SUBMISSION OUTCOME: Administratively Acknowledged

IBC# 23005 Full Renewal Expiration Date: 05/31/2026

Chanwit Roongsritong, MD/TTUHSC El Paso - SOM - Internal Medicine-Texas Tech Medical Center

Biosafety Level: BSL 2

ADMINISTRATIVE COMMENT:

Comment:

Personnel change to add Daniel De Leon. COI, FD, and LSE are complete. This protocol does not involve recombinant or synthetic nucleic acid molecules.

RECOMMENDATIONS: Acknowledged

SUBMISSION OUTCOME: Administratively Acknowledged

TERMINATIONS

N/A

BSO REPORT

Safety Services provided a tentative inspection schedule, an update on SciShield status, and shared key takeaways from AAALAC regarding eyewash stations and emergency showers.