UTHealth Institutional Biosafety Committee (IBC)

Title: Fully and Conditionally Exempt Institutional Biosafety Committee Protocols

Original Date: January 2013 **Revision Date:** September 14, 2023

The Institutional Biosafety Committee (IBC) has identified work that does not require full committee review. Protocols that do not require full IBC committee review can be classified as Full Exemption or Conditionally Exempt.

The Institutional Biosafety Committee (IBC) regularly receives protocols requesting approval for the collection, shipment, storage and manipulation of human biological specimens that are done as part of an IRB approved clinical study. Additionally, the IBC regularly receives protocols requesting the use of human cell lines without rDNA will be stored and/or analyzed, work with Risk Group 1 (RG1) organisms and exempt rDNA work as defined by the NIH guidelines (III-F).

EHS will be given the authority by the IBC to review and determine exemption status of protocols. EHS will have authority to approve protocols considered "Conditionally Exempt" based on numerous previously conducted risk assessments performed by the committee.

Protocols meeting Criteria for Full Exemption

1. Collection of human samples (i.e. blood, urine, tissue, etc.) as part of a clinical study, then prepared and shipped for off-site analysis (non-UTHealth site, sponsor, or reference laboratory) or point-of-care diagnostics as part of standard clinical care
2. Cultures of RG-1 organisms considered non-infectious and not containing rDNA
    a. Possession, collection, processing, and manipulation for research when volumes of pure culture do not exceed 10L and manipulations minimize aerosolization potential
3. Exempt rDNA

Steps for a Fully Exempt Protocol:

1. Protocol is not required to be submitted to EHS.
2. Protocol may be received via the online protocol submission system.
3. Protocol is reviewed by a biological safety staff member.
4. If the protocol is found to meet the Full Exemption Criteria, an IBC number can be assigned to the protocol and moved to EXEMPT status.
5. EHS can notify the PI of the EXEMPT status.

Protocols meeting Criteria for Conditionally Exempt:

1. Human blood, bodily fluids, or tissue samples collected, storage and analyzed in a lab at UTHealth.
    a. Samples presumed to not harbor BBP or infectious disease that can be transmitted by manipulation of the sample
    ex: patients screened for HIV, HBV, HCV. If samples come from HIV-positive patients, then full IBC committee review is required.
    b. Molecular and biochemical analysis with the absence of rDNA
2. Human cell lines used in research in labs at UTHealth, in the absence of rDNA.

Steps for a Conditionally Exempt Protocol:

6. Protocol is received via the online protocol submission system.
7. Protocol is reviewed by a biological safety staff member.
8. If other potentially infectious agents are known to be in the sample or if the work involves a potentially infectious microorganism or recombinant or synthetic DNA, it must go to the committee for full review. At the discretion of the EHS Biological Safety program, a conditionally exempt protocol can be directed to the committee for full review.
9. Work with the PI/PI staff to ensure a complete protocol is produced. The protocol must outline compliance with the OSHA bloodborne pathogen standard, the CDC NIH Biosafety in Microbiological and Biomedical Laboratories, and the UTHealth Institutional Biosafety manual.
10. The MUA to be signed specifically states the PI will adhere to stated compliance requirements and will be included in the monthly IBC meeting packet.
11. Provide an approval memo to PI.
12. List protocol on IBC agenda under “Conditionally Exempt Protocols” and provide a brief review of the protocol upon the Committee’s request.
13. File a copy of the signed protocol and approval memo in EHS office.
14. The protocol will follow the 5-year renewal cycle as an approved protocol.

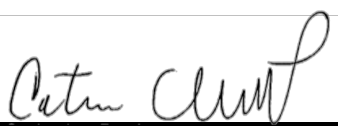
The University of Texas Health Science Center at Houston
Guidance on "Do I Need IBC Approval?"

Material	Manipulations	IBC Review Needed?	
		No	Yes
Human blood, bodily fluids, or tissue samples	Collection, preparation for shipment off-site	X	
	Collection, storage, processing, and/or manipulation for research		X**
Human cell lines	Collection, processing, and/or manipulation for research		X**
Recombinant or synthetic nucleic acids – including viral vectors	*See NIH Guidelines*		X
Pure cultures of non-infectious microorganisms (Risk Group I*) or materials containing RG I microbes	Possession, collection, processing, and manipulation for research when volumes of pure culture do not exceed 10L and manipulations minimize aerosolization potential.	X	
Pure cultures of infectious microorganisms (≥ RG II) or materials containing infectious substances	Possession, collection, processing, and/or manipulation for research		X
Samples of soil, water, animals, plants, or insects **known to be free** of pathogens	Collection, processing, and/or manipulation for research	X	
Samples of soil, water, animals, plants, or insects **suspected or known to contain** pathogens	Collection, processing, and/or manipulation for research or shipment		X

*Risk Group I organisms are not known to cause disease in healthy human adults[1]. A partial list is available here.
Risk Group II organisms are known to cause limited or treatable disease in healthy human adults[1]. The links above also include RG II organisms.
Risk Group III organisms are known to cause serious or lethal human disease with limited treatments available[1]. The links above also include RG III organisms.
Risk Group IV organisms are known to cause serious or lethal human disease and have no available treatments[1]. The links above also include RG IV organisms. UT Health does not perform work with RG IV organisms.

1: Chosewood, L. Casey, and Deborah E. Wilson. *Biosafety in microbiological and biomedical laboratories*. Diane Publishing, 2007.
**May meet Conditionally Exempt Criteria

This policy has been reviewed and approved by the Institutional Biosafety Committee.

X 

Institutional Biosafety Committee Chair