INSTITUTIONAL BIOSAFETY COMMITTEE STANDARD OPERATING PROCEDURE		
SOP Title: Administrative Review of Research Applications Using Human/Nonhuman Primate Cell Lines		
SOP Number: IBC-PP-008	Revision Number: 3	Section: Biosafety
Author: Patricia Cox		Effective Date10/7/09

1. Purpose

   1.1. This procedure refers to IBC applications only.

   1.2. The purpose of this procedure is to describe the process for administrative review of research involving the use of human /nonhuman primate cell lines that are not deliberately infected with a pathogenic/recombinant/synthetic organism, altered through recombinant DNA technology or known to contain a pathogen or other biohazardous material.

   1.3. Background: In 1994, OSHA issued an interpretation of the applicability of the Bloodborne Pathogens (BBP) Standard towards human cell lines. According to the interpretation, human cell lines are considered to be potentially infectious and within the scope of the BBP Standard unless the specific cell line has been characterized to be free of hepatitis viruses, human immunodeficiency virus, Epstein-Barr virus, papilloma viruses and other recognized bloodborne pathogens.

   Based upon the above interpretation, any work with human or nonhuman primate cell culture requires the submission of an IBC application, BSL-2 laboratory certification and bloodborne pathogens training by all personnel handling the cells.

   Because the majority of cell lines used on campus are common and well characterized, the process of approving applications using such cell lines may be done through administrative review conducted by the BSO and IBC Chair as long as the conditions of 1.2 are met.

2. Key Word Definitions

   2.1. BSO: Biological Safety Officer

   2.2. IBC: Institutional Biosafety Committee

   2.3. PI: Principal Investigator

   2.4. Administrative Review: review of research by the Biological Safety Officer and IBC Chair

   2.5. OSHA: Occupational Safety and Health Administration

3. Responsibilities and Authorities

3.1. Biological Safety Officer

3.1.1. Processes new applications;

3.1.2. Determines if the application can undergo administrative review;

3.1.3.Informs the IBC Chair of the application;

3.1.4.Reviews the application;

3.1.5.Fills out IBC Risk Assessment Checklist;

3.1.6. Writes letters related to application and sends to PI;

3.1.7. Monitors fulfillment of IBC requirements for work with human/primate specimens;

3.1.8. With IBC Chair, gives final approval when all requirements are met;

3.1.9. Maintains applications and any associated paperwork;

3.2. IBC Chair

3.2.1. With BSO, gives approval when conditions are met;

3.2.2. May also choose to delegate review to another IBC member.

4. Items Needed

4.1. IBC application

5. Procedure

5.1. Upon submission of an IBC application, the BSO will determine the type(s) of cell line(s) to be used and the manipulations that are planned for each line. If the cell lines are not to be deliberately infected with a pathogenic/recombinant/synthetic organism, altered through recombinant DNA technology, known to already contain a pathogen or other biohazardous material, the BSO may contingently approve the application. The BSO will forward application to the IBC Chair for Chair review.

5.2. Other requirements to work with human/nonhuman primate cell lines must be met before final approval.

5.3. When all requirements are met, the BSO and IBC Chair will approve the application.

5.4. The BSO will provide written approval to the PI.

5.5. The IBC will be informed of the approved work at the next scheduled meeting.

5.6. If the BSO/ IBC Chair determine that the research outlined in the application is outside of the stated parameters in Section 1.2 or that the application warrants full review by the IBC, the application will be processed and reviewed as per IBC-PP-012.

6. Associated SOPs

6.1. IBC-PP-012 IBC Application Submission Review and Approval

7. Associated Forms

7.1. IBC application

7.2. Risk Assessment Checklist

8. References

8.1. *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* Section IV-B-2.

8.2. Biosafety in Microbiological and Biomedical Laboratories

9. Revision History

9.1. Revised on 3/28/13 and approved on 5/15/2013

9.2. Revised on 8/24/2015 and approved 9/16/2015

9.3. Revised on 11/29/2016 and approved 1/18/2017

10. Approvals

INSTITUTIONAL BIOSAFETY COMMITTEE STANDARD OPERATING PROCEDURE		
SOP Title: Administrative Review of Research Applications Using Human/Nonhuman Primate Cell Lines		
SOP Number: IBC-PP-008	Revision Number: 3	Section: Biosafety
Author: Patricia Cox		Effective Date10/7/09

Reviewed by: _____ Date Reviewed: _____
Biological Safety Officer

Approved by: _____ Date Approved: _____
IBC Chair