

# POLICY AND PROCEDURE MANUAL

<b>Pennington Biomedical</b>	<b>Policy No. 106.00</b>	<b>Origin Date: 3/17/09</b>
<b>Impacts:</b>	<b>All Personnel</b>	<b>Effective: 11/20/15</b>
<b>Subject:</b>	<b>Regulatory Compliance Training</b>	<b>Last Revised: 5/24/2021</b>
<b>Source:</b>	<b>Executive Director and Director of Legal and Regulatory Compliance</b>	<b>Version No. 12</b>

## PURPOSE

Regulatory and compliance training is required for all employees and is a condition of employment. Employees who fail to comply with compliance educational requirements can be subject to disciplinary action, up to and including termination. Appendix A of this policy outlines the frequency and training requirements for each population at Pennington Biomedical Research Center (Pennington Biomedical).

## AUTHORITY

The Executive Director is responsible for ensuring that all employees have completed their regulatory training as required by law. This authority may be delegated to a member of the Quality Improvement Committee and/or the Director of Legal and Regulatory Compliance.

## ENFORCEMENT

The employee receives an automated email notice at the time of the compliance assignment and an automated reminder email at a pre-determined time prior to the compliance's due date. If the employee fails to complete the training by the due date and has not contacted the Director of Legal and Regulatory Compliance or his/her designee, for an extension, a late notice email will be sent to the employee and the employee's supervisor.

If the training is not completed after a pre-determined time, Pennington Biomedical Security will revoke the employee's identification and access badge privileges. The employee must complete the compliance training before Security re-activates the identification and access badge.

**Compliances listed below are assigned electronically and only to those individuals who have login IDS**

<b><u>Name of Training</u></b>	<b><u>Individuals required to take training (Audience)</u></b>	<b><u>Frequency of Training</u></b>	<b><u>Name of legal, regulatory or policy requirement training fulfills</u></b>
<b>ANIMAL SUBJECTS PROTECTIONS</b>			
CBC Orientation	All new animal user employees	When access to CBC is requested	PHS Service Policy "The Guide" and IACUC
CITI laboratory Animal Training	All employees who need card access to CBC or become appointed to the IACUC. This program is separated by level of authority with different requirements deemed by the IACUC: Group 1 (i.e., "Faculty and post doc") Group 2 (i.e., "All members of the IACUC") Group 3 (i.e., "RA, students, and volunteers")	When access to CBC is requested (i.e., Groups 1 & 3) When appointed to the IACUC (i.e., Group 2)	PHS Service Policy "The Guide" and IACUC
Surgery Orientation	Employees who are on protocols that require them to do surgery on animals	As protocols come through the IACUC and researcher requests training	PHS Service Policy "The Guide" and IACUC
<b>HUMAN RESOURCE MANAGEMENT</b>			
Background Check	Effective July 2016 required for all hires; All security personnel and any PBRC employees who will take custody of a minor	One time upon designation by new employee settings	DCFS and institutional policy LSU PM-16
Computing Resource Agreement	All current PBRC employees, visiting scholars, trainees, and external users	Annually	HIPAA Security 45 CFR § 164.530
Drug Free Workplace	All current PBRC employees, visiting scholars, and trainees	Within 90 days of hire and once every 5 years	Federal Drug Free Workplace Act of 1988; Louisiana Drug Testing Act of 1990; PM-33; ORM Safety Program; and PBRC policy 512.00
Mandatory Reporter Training	Any PBRC employees who will take custody of a minor	Annually	DCFS and institutional policy LSU PM-16
PM-16 Minors Program Training	Required for any PBRC employees, who will take custody of a minor	Annually	DCFS and institutional policy LSU PM-16
Return to Work Policy	All current PBRC employees, and visiting scholars	Annually	LA R.S. 42:1170 and PBRC policy 913.00
Sexual Harassment Training	All current PBRC employees, visiting scholars and trainees.	Annually	LA RS 42:343 and PBRC policy 910.00.
Sexual Harassment Training - Supervisors	All current PBRC Supervisors	Annually	LA RS 42:343 and PBRC policy 910.00
SMART Background Check	SMART Background Check required for any PBRC Employees who will take custody of a minor	Every three years	DCFS and institutional policy LSU PM-16
Violence in the Workplace	All current PBRC employees, visiting scholars, and trainees	No longer considered mandatory by ORM Safety Program but encouraged to continue program.	PBRC policy 923.00

## HUMAN SUBJECTS PROTECTIONS

CITI Human Subjects Research Training (Biomedical Research & Good Clinical Practices)	All individuals who interface with research participants, research participant biological specimens or research participant data.	Every three years	Human Research Protections Program Policy 302.00; NOT-OD-00-039; NOT-OD-1-061
CITI IRB Administration	IRB members and Human Research Protections staff	Every three years	Human Research Protections Program Policy 302.00
Clinical Investigator Training	Faculty members who are investigators and doing clinical research	At time of hire and/or once begin clinical research work	Internal Policy
HIPAA Privacy and Security Breaches	All PBRC employees who are designated HIPAA High status (works with PHI)	Annually	HIPAA Security and Privacy Training 45 CFR § 164.530
HIPAA Privacy High Risk	All PBRC employees who are designated HIPAA High status (works with PHI)	Annually	HIPAA Security and Privacy Training 45 CFR § 164.530
HIPAA Privacy Low Risk	Any PBRC employee who is not designated HIPAA High status	Annually	HIPAA Security and Privacy Training 45 CFR § 164.530
HIPAA Security End User	All current PBRC employees, visiting scholars, trainees	Annually	HIPAA Security and Privacy Training 45 CFR § 164.530
Home Visitation	All individuals who interface with research participants, research participant biological specimens or research participant data.	Every two years	Internal Policy

## LEGAL AND REGULATORY

Administration and Legal Compliance Reminders	All current PBRC employees, visiting scholars, trainees	Annually	Internal Policy
CITI FCOI training	All current PBRC employees, visiting scholars, and trainees who are faculty or designated by their employee setting as working on any research conducted through PBRC's assurance committees.	Every two years	PBRC policy 401.00; 45 CFR 50.604 Prior to engaging in research related to PHS-funded grant and at least every four years
Code of Conduct	All current PBRC employees, visiting scholars, and trainees	Annually	OIG Guidance on Compliance Program for Recipients of PHS Awards
Cybersecurity Awareness	All current PBRC employees, visiting scholars, and trainees	At the time of hire, within thirty (30) days and annually.	LA R.S. 42.1267
Ethics Training	All current PBRC employees, visiting scholars, trainees	Annually	LA R.S. 42:1170 and PBRC policy 931.00
Financial Conflicts of Interest Disclosure	All current PBRC employees, visiting scholars, and trainees	At time of hire, within thirty (30) days of change in interest and annually.	PBRC policy 401.00 and 45 CFR 50.604
Financial Conflict of Interest Read and Agree	All current PBRC employees, visiting scholars, and trainees who are <u>not</u> faculty or designated by their employee setting as working on any research conducted	Every two years	PBRC policy 401.00 and 45 CFR 50.604
Whistleblower Policy Read and Agree	All current PBRC employees, visiting scholars, trainees	Annually	Statutory whistleblower laws, including but not limited to 42 CFR Part 93, 45 CFR 164.530(g), 41 USC 4712, LA R.S. 23:968, and LA 39:2163

**SAFETY**

Blood Borne Pathogen	Low Risk Individuals	Within 90 days of hire and annually thereafter - If there is a BBP event, retraining is required within 60 days of when the event occurred	Required by ORM Safety Program.
Blood Borne Pathogen/ Laboratory Biosafety	High Risk Individuals	Within 90 days of hire and annually thereafter - If there is a BBP event, retraining is required within 60 days of when the event occurred	Required by ORM Safety Program.
CITI Biosafety Training	All current PBRC employees, visiting scholars, trainees who work with biohazards	One time - Upon designation by new employee settings	Required by ORM Safety Program
Emergency Procedures	All current PBRC employees, visiting scholars, and trainees	Annually	Clinic SOP 802
General Safety Rules	All current PBRC employees, visiting scholars, and trainees	Annually	Required by ORM Safety Program
Hazardous Communication	All current PBRC employees, visiting scholars, and trainees	Annually	Required by ORM Safety Program
Hazardous Waste Training	Required for all employees who handle hazardous chemicals in the workplace	Annually	"EPA recommends annual training"
Medical Clearance for N95s	Employees required to wear an N95 respirator as part of their job duties	Annually	Required by OSHA and Recommended by AAALAC
OH&SP	All employees who have access to CBC	When access to CBC is requested	PHS Service Policy "The Guide" and IACUC
OH&SP—12 month	CBC staff and researchers whose risk assessment is classified at a level 3; use Chemical and biological hazards	Every 12 months	PHS Service Policy "The Guide" and IACUC
OH&SP—24 month	Employees whose risk assessment is classified at a level one or 2. This would include students who have access to CBC.	Every 24 months provided risk assessment has not changed to a level 3	PHS Service Policy "The Guide" and IACUC
Safety Manual	All current PBRC employees, visiting scholars, and trainees	Annually	Required by ORM Safety Program
Tetanus Awareness	All employees that work with animals	Annually	LSU Campus Physician and "The Guide"
Defensive Driving Notice	All current PBRC employees, visiting scholars, and trainees	Annually	In support of compliance with ORM Driver Safety Program
Active Threat Response	All current PBRC employees, visiting scholars, and trainees	Annually	PBRC Policy 1004.00

## Training requirements required by Investigators not assigned in Compliance Manager

<u>Name of Training</u>	<u>Individuals required to take training (Audience)</u>	<u>Frequency of Training</u>	<u>Name of legal, regulatory or policy requirement training fulfills</u>
<b>FACILITIES MANAGEMENT</b>			
Driving on State Business	All current PBRC employees, visiting scholars, and trainees	Every 3 years	State of Louisiana – Division of Administration Office of Risk Management
<b>HUMAN RESOURCES MANAGEMENT</b>			
Performance Evaluation System (PES) Training	Classified Employee Supervisors	Annually	PBRC Policy 920.00
<b>HUMAN SUBJECTS PROTECTIONS</b>			
Department of Defense Educational Requirements	Those employees participating on DOD protocols and grants	In accordance with DOD requirements	DOD directive 3216-02 Principal Investigator is responsible for meeting the specific DOD education requirements.
<b>SPONSORED PROJECTS / DIVISION OF EDUCATION</b>			
Responsible Conduct of Research	<p>All trainees, fellows, participants and scholars receiving support through any applicable NIH training, career development award, and research education grant and any other NIH-funded programs supporting research training, career development, or research education that require instruction in RCR as stated in the funding opportunity announcements.</p> <p>All undergraduate and graduate students and post-doctoral students and post-doctoral fellows who will be supported by NSF to conduct research.</p>	Instruction must be undertaken at least once during each career stage and at a frequency of no less than once every four years.	NIH and NSF regulations: NIH policy NOT-OD-10-019

## Pennington Biomedical Research Foundation Employees

### Required Compliances

- Computing Resource Agreement
- HIPAA Security End User
- Emergency Procedures
- General Safety Rules

\*\* Refer to training matrix for additional compliance information \*\*

### Position Types:

<u>TYPE</u>	<u>DEFINITION</u>
Adjunct	Faculty appointment whose primary employment is outside PBRC. <b>** Effective January 18, 2017 – Adjunct Faculty will no longer receive PBRC compliance assignments **</b>
Current PBRC Employee / Student	Student - A college student
External User	Non PBRC employees who are external to the PBRC organization and who need access to the PBRC computing resources including contractors and nonemployee collaborators. <b>** Effective April 2020 – External Users need to only complete HIPAA Security End User and Computing Resource Agreement compliances electronically through the EU request system every 6 months. And not through Compliance Manager **</b>
Foundation	An individual whose primary employment is with the Pennington Biomedical Research Foundation.
Gratis / Visiting Scholar	Gratis - A non-paid employee who holds honorary distinction. Visiting Scholar – Faculty from another institution of higher education who are on a temporary duty assignment, to learn a particular skill, method or receive other training.
LSU System @ PBRC	LSU System employees who are collaborating with PBRC and may have physical and electronic access.
Third Party Affiliate	An individual who is an employee of a third-party company affiliated or collaborating with PBRC.
Trainee (1 & 2)	A Non PBRC employee admitted into the PBRC trainee program
W.A.E. (While Actually Employed)	A temporary assignment on an “as-needed-basis”.



## Policy Committee Secretary's Attestation

Date of Policy Committee Meeting: Expedited email review of revised policy 11/12/2015

Policy #: 106.00, Regulatory Compliance Training

Date of Approval: 11/20/2015

Publication Date: 12/7/2015

Effective Date: 11/20/2015

*Anne Duke*

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Anne Duke, Policy Committee Secretary

*11/20/15*

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Date

## Approval by the Executive Director

*William T. Cefalu, MD*

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William T. Cefalu, MD  
Executive Director

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Date