

POLICY AND PROCEDURE MANUAL

Pennington Biomedical	POLICY NO. 106.00	Origin Date:3/17/2009
Impacts:	All personnel	Last revised: 11/20/2015
Subject:	Regulatory Compliance Training	Effective: 11/20/2015
Source:	Executive Director and Director of Legal and Regulatory Compliance	Version No. 5

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.

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, PBRC's 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.

The compliances listed below are assigned electronically and only to those individuals who have login IDs

<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>
ANIMAL SUBJECTS PROTECTIONS			
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 want to gain card access to CBC and are new to the center. This program is separated by level of authority in the protocols- PI, RA and students have different requirements deemed by the IACUC.	When access to CBC is requested	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
HUMAN RESOURCE MANAGEMENT			
Background Check	All security personnel and any PBRC employee who takes custody of a minor (Starting July 2016 this compliance will be required for all hires)	One time upon designation by new employee settings	DCFS and institutional policy
Computing Resource Agreement	All current PBRC employees, visiting scholars, trainees and external users	Upon hire or granting network access	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 employee who deals with minors	Annually	DCFS and institutional policy
PES Training	Classified Employee Supervisors	Annually	PBRC policy 920.00

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Return to Work Policy	All current PBRC employees, and visiting scholars	Annually	LA R.S. 42:1170 and PBRC policy 913.00
Title IX/Sexual Harassment Training	All current PBRC employees, visiting scholars and trainees.	Annually	Senate Resolution 107 requires all public servants to receive one hour of sexual harassment training each year. Required by ORM Safety Program and PBRC policy 910.00.
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	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
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.
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

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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 PBRC employees who are designated HIPAA High status (works with PHI)	Annually	HIPAA Security and Privacy Training 45 CFR § 164.530
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
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
Responsible Conduct of Research	All trainees, fellows, participants and	Instruction must be undertaken at least	NIH and NSF regulations:

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	<p>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 fellows who will be supported by NSF to conduct research.</p>	<p>once during each career stage and at a frequency of no less than once every four years.</p>	<p>NIH policy NOT-OD-10-019</p>
<p>Whistleblower Policy Read and Agree</p>	<p>All current PBRC employees, visiting scholars, trainees</p>	<p>Annually</p>	<p>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</p>
SAFETY			
<p>Blood Borne Pathogen</p>	<p>Low Risk Individuals</p>	<p>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</p>	<p>Required by ORM Safety Program.</p>
<p>Blood Borne Pathogen/ Laboratory Biosafety</p>	<p>High Risk Individuals</p>	<p>Within 90 days of hire and annually thereafter -If there is a BBP event</p>	<p>Required by ORM Safety Program.</p>

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		, retraining is required within 60 days of when the event occurred	
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	One time-Upon designation by new employee settings	ORM Safety Program
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, physical plant staff 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
Tetanus Awareness	All employees that work with animals	Every 10 years	LSU Campus Physician and "The Guide"



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

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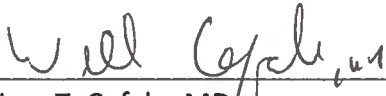


Anne Duke, Policy Committee Secretary



Date

Approval by the Executive Director



William T. Cefalu, MD
Executive Director

Date