1. **PURPOSE**
	1. This procedure establishes the process to conduct For-Cause Directed Reviews.
	2. The process begins when a question relating to non-compliance (perceived or confirmed) is raised. A directed review may be required as a result of:
		1. Reportable events.
		2. Any review of submitted materials.
		3. Any allegation of non-compliance (perceived or confirmed), upon HSPP notification Request For-Cause audit by the IRB.
		4. A suspension or termination of IRB approval (see HRP-026).
		5. Request by an IRB Chair, convened IRB Committee, IRB Directors, or Institutional Official.

1.2.2 A routine review is chosen by a random sampling of active studies approved by the IRB.

1.2.2.1 Sampling of minimal risk studies

1.2.2.2. Sampling of greater than minimal risk studies

1.2.2.3 Sampling of device studies

1.2.2.4 Sampling of clinical trials with an IND

1.2.2.5 Sampling of social and behavioral studies

* 1. The process ends when:
		1. A directed review is deemed not required
		2. The For-Cause report has been submitted to the Institutional Review Board (IRB) and the Institutional Official and a determination has been made that additional investigation of the alleged noncompliance is not needed.

1. **PREVIOUS VERSION**
	1. None.
2. **POLICY**
	1. The HSPP has the responsibility to maintain a review program to monitor and improve compliance in identified problem areas.
	2. The HSPP investigates concerns, allegations, complaints on non-compliance, and systematic problem areas in Human Subjects Research.
3. **RESPONSIBILITIES**
	1. Institutional Official or designee:
		1. Requests that the HSSP Analysts review the Investigator and study materials as needed to answer the questions raised by the review of non-compliance or other eIRB submission.
		2. Provides the HSPP Analysts Office with the scope of the review.
	2. Upon notification of the For-Cause review, the HSPP Analysts create a review plan and carry out these procedures.
	3. The HSPP Analysts make their findings based on the available materials, interviews, and/or information obtained during the For-Cause Review.
	4. The HSPP Analysts will document their findings in writing in the form of a report and submit it to the IRB.
4. **PROCEDURE**
	1. The Director, HSPP Analysts will notify the investigator that a For-Cause Review will be conducted.
	2. The HSPP Analysts schedule an on-site review of the protocol identified in 5.1.
	3. The HSPP Analysts, in consultation with the Director HSPP Analysts, determine what information to gather and what individuals to interview.
		1. The HSPP Analysts prepare and maintain the For-Cause Review file, which typically consists of the following elements (but may vary depending on the circumstances of a particular For-Cause Review):
			1. IRB Submission
			2. Consent Document(s)
			3. Protocol(s)
			4. Investigators Brochure(s)
			5. Protocol Modification(s)
			6. Continuing Reviews
			7. Post Approval Monitoring Checklists (HRP-430a-e)
			8. Report (official For-Cause Review report)
			9. Significant Findings/Determinations
	4. Gather information and interview individuals.
		1. Based on the nature of the concerns, this might involve one or more of the following activities:
			1. Interviewing research staff
			2. Reviewing regulatory and all applicable documentation
			3. Reviewing either a random sample or all of the consent forms)
			4. Reviewing either a random sample or all of data or case report forms
	5. The HSPP Analysts complete HRP-430c for studies classified as biomedical research
	6. The HSPP Analysts complete HRP-430d for social-behavioral research studies
	7. The HSPP Analysts will document their findings in writing and submit it to the IRB.
		1. This documentation will include the following:
			1. Background and Summary
			2. Findings and/or observations
			3. Supporting evidence
5. **MATERIALS**
	1. HRP-024 - SOP – Reportable New Information
	2. HRP-026 - SOP - Suspension or Termination Issued Outside of Convened IRB
	3. HRP-101 - SOP - Human Research Protection Program Plan
	4. HRP-430a - CHECKLIST - Post Approval Monitoring Self-Assessment Drug or Device Clinical Trial
	5. HRP-430b - CHECKLIST - Post Approval Monitoring Self-Assessment Participant File
	6. HRP-430c - CHECKLIST - Post Approval Monitoring Self-Assessment Biomedical Research
	7. HRP-430d - CHECKLIST - Post Approval Monitoring Self-Assessment Social Behavioral Research
	8. HRP-430e - CHECKLIST - Post Approval Monitoring Self-Assessment – Humanitarian Use Device
6. **REFERENCES**
	1. Rutgers University
		1. HRP 101 Rutgers Human Subjects Protection Program (HRP-101)
		2. Rutgers HSPP Toolkit and Guidance
	2. *Federal Regulations:*
		1. 21 CFR Part 11 – Electronic Records; Electronic Signatures
		2. 21 CFR Part 50 – Protection of Human Subjects
		3. 21 CFR Part 54 – Financial Disclosures by Clinical Investigators
		4. 21 CFR Part 56 – Institutional Review Boards
		5. 21 CFR Part 312 Investigational New Drug Application
		6. 21 CFR 314 Applications for FDA Approval to Market a New Drug
		7. 21 Part 600 – Biological Products: General
		8. 21 CFR 601 – Applications for FDA Approval of a Biologic License
		9. 21 CFR 812 – Investigational Device Exemptions
		10. 21 CFR Part 814 – Premarket Approval of Medical Devices
		11. 45 CFR Part 46 HHS – Protection of Human Subjects
		12. 45 CFR Parts 160 and 164 HIPAA Privacy Rule

*7.3 New Jersey State Law:*

*7.3.1 Title* 26 Chapter 316 - Access to Medical Research Act