1. PURPOSE
	1. This document describes the procedures for appealing a determination by the SUNY New Paltz HREB.
2. REVISIONS FROM PREVIOUS VERSION
	1. None
3. POLICY
	1. The SUNY New Paltz HREB has the authority to a) approve research activity, b) specify modifications required to secure HREB approval of the research activity, c) disapprove any research activity overseen and/or conducted by SUNY New Paltz, or d) suspend research activity on a specific protocol or by a specific researcher.
	2. The HREB has the authority to suspend or terminate approval of research that is not conducted in accordance with HREB policies, is not in compliance with applicable Federal Regulations, or that is associated with unexpected serious harm to participants.
	3. Research approved by the HREB may be subject to further review by officials at SUNY New Paltz as part of the Human Research Protection Program (HRPP), as appropriate. HRPP officials may override the HREB’s decision to approve research; however, they may not approve the research if it has not been approved by the HREB or overrule other decisions made by the HREB.
	4. Investigators may appeal:
		1. Revisions required by the HREB;
		2. HREB determinations of non-compliance, serious non-compliance, continuing noncompliance, or an unanticipated problem involving risks to participants or others;
		3. HREB disapproval of research; and
		4. Termination of an approved protocol by the HREB
	5. A researcher may appeal to the Human Protections Administrator for the HREB to do a formal re-review of a decision. The only grounds for requesting an appeal are when:
		1. There have been multiple unsuccessful efforts by the researcher and the HREB to resolve a disagreement; and
		2. The researcher believes that the HREB’s decision is due to:
			1. Inadequate or inaccurate information;
			2. HREB non-compliance with University policy, state law, or federal regulation.
4. RESPONSIBILITIES
	1. In the case of an appeal, the campus Human Protections Administrator will conduct the appeal process.
5. PROCEDURE FOR REQUESTING AN APPEAL
	1. If an investigator disagrees with a revision requested by the HREB, the investigator may submit a written appeal to the Human Protections Administrator who was responsible for issuing the request. The investigator should include information supporting any arguments made in the appeal.
	2. Requesting an Appeal
		1. The appeal must be requested by the researcher within 30 days of the date of the most recent HREB decision (as documented in PACS) related to the decision being appealed.
		2. The appeal request consists of sending the Human Protections Administrator:
			1. A cover letter outlining the basis for the appeal.
			2. All electronic documents that support the appeal.
			3. All documents should come as a single PDF file and submitted to hpa@newpaltz.edu, hrebchair@newpaltz.edu, and hrebcoordinator@newpaltz.edu.
		3. Within three business days of receipt, the Human Protections Administrator:
			1. Provides the relevant Campus Signatory with a copy of the materials; and
			2. Sends the researcher an acknowledgment of receipt of the appeal request.
		4. The appeal is heard at an HREB meeting. This may be a regularly scheduled HREB meeting, or it may be a meeting convened specifically for this purpose.
		5. The researcher is required to attend the HREB meeting and to present the appeal to the HREB members. The Human Protections Administrator works with the HREB and the researcher to schedule a mutually-acceptable review date as soon as possible.
		6. Attendees for the appeal portion of the HREB meeting include:
			1. The researcher
			2. Up to two colleagues or staff of the researcher (if desired)
			3. Quorum of the HREB
			4. Human Protections Administrator
	3. During the HREB Full Board meeting:
		1. The HREB Chair may hold a closed session without the researcher and colleagues, prior to the appeal portion of the meeting, to establish the key issues and questions to consider.
		2. The researcher is invited to present information and rationale to the HREB.
		3. The researcher’s colleagues (if present) are invited to present.
		4. There is a question-and-answer session with the researcher and colleagues.
		5. The researcher and colleagues leave the meeting room.
		6. The HREB members and other meeting attendees discuss the appeal.
		7. The Human Protections Administrator prepares anonymous written ballots to distribute to the members for voting when the discussion has ended. After voting, the ballots are read by the HPA. The HREB moves and then votes whether to take one of the following actions:
			1. Approve the appeal and modify the original decision;
			2. Disapprove the appeal and uphold the original determination; or
			3. Defer the appeal and obtain additional information or consultation in order to make a final decision.
	4. Appealing an HREB Full Board Decision
		1. If a researcher is not satisfied with the result of the HREB outcome described in 5.3, the researcher can submit an appeal to the Signatory Official.
		2. Follow the same process in Section 5.2 for submitting this second appeal.
		3. The Signatory Official will examine the materials presented by both the researcher and the HREB and make one of the following determinations:
			1. Send the appeal back to the HREB for further review;
			2. Send the appeal to the Human Protections Administrator for further review; or
			3. Reject the appeal.
6. REFERENCES (This policy was based on the following)
	1. [Institutional Review Board – The University of Utah](https://irb.utah.edu/_pdf/IRB%20SOP%20410%20version%20051818.pdf)
	2. [University of Tennessee Health Science Center IRB Appeal of IRB Decisions](https://www.uthsc.edu/research/compliance/irb/researchers/documents/appeal-of-irb-decisions.pdf)
	3. [University of Washington – Appeal of IRB Determination](https://www.washington.edu/research/wp/wp-content/uploads/2017/01/SOP-Appeal-of-IRB-Determination.docx)