#  Human Research Ethics Board

1. Mission
	* 1. The mission of the Human Research Ethics Board is to work with and educate the research community of the State University of New York at New Paltz to protect the rights and welfare of human participants in research conducted in affiliation with the College, ensuring compliance with the legal requirements and ethical principles of Respect for Persons, Beneficence, and Justice.
	1. Policy
		1. The State University of New York at New Paltz (University as used in this document) fosters a research environment that promotes respect for the rights and welfare of individuals recruited for, and participating in, research conducted by or under the auspices of the University. In the review and conduct of research, actions by the University will be guided by the principles set forth in [The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects in Research](https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html) by the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research. These principles are:
			1. **Respect for Persons**, which involves the acknowledgment and support of autonomy, and protection of those with diminished autonomy
			2. **Beneficence**, which involves ensuring that possible benefits of research are maximized, and possible harms are minimized
			3. **Justice**, which involves the fair distribution of the benefits and burdens of research through the equitable selection of participants
		2. The actions of the University will also conform to all applicable federal, state, and local laws and regulations. In order to fulfill this policy, the University has established a human research protections program (HRPP).
	2. Definitions
		1. Relevant definitions can be found on the HREB’s Website (see section 9 of this document) in the document: [NP SOP 2019 Definitions](https://www.newpaltz.edu/media/sponsored-programs/NP%20SOP%202019%20Definitions.docx).
			1. **Research subject to regulation** and similar terms are intended to encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity. It does not include research activities which are incidentally regulated by a federal department or agency solely as part of the department's or agency's broader responsibility to regulate certain types of activities whether research or non-research in nature (for example, Wage and Hour requirements administered by the Department of Labor).
	3. Ethical Principles
		1. The State University of New York at New Paltz acknowledges and accepts its responsibility for protecting the rights and welfare of human participants of research. Since the conduct of research with human beings may raise fundamental ethical and civil rights questions, no distinctions in the monitoring of projects will be drawn between funded and non-funded projects, or between projects carried out by students, faculty, staff, agents, or affiliate researchers (on-campus or off-campus). SUNY New Paltz is guided by the ethical principles regarding all research involving humans as participants, as set forth in the Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled, Ethical Principles and Guidelines for the Protection of Human Subjects of Research, (The "Belmont Report"). SUNY New Paltz complies with Federal laws requiring the protection of human research participants. Notations occurring in the State University of New York at New Paltz Policy on the Use of Human Subjects in Research are taken from Title 45, Code of Federal Regulations, Part 46 (45 CFR 46) unless otherwise indicated.
		2. The HREB will ensure that all human subject research, regardless of funding source, for which the HREB provides review and oversight, complies with 45 CFR 46 and all of its subparts (A, B, C, D). All federally supported human subject research will also comply with any additional human subject regulations and policies of the supporting Department or Agency. All federally supported human subject research will comply with any human subject regulations and policies of any relevant regulatory Department or Agency.
		3. The following principles apply equally to all research involving human beings, whether carried out with University resources or with the assistance of outside funds. SUNY New Paltz assumes responsibility for communicating and explaining these principles to personnel and students and for providing procedural guidelines to affect their Compliance. All faculty members, staff, students, agents, and affiliate researchers who anticipate conducting research projects (on or off campus) involving human participants are responsible for familiarizing themselves and complying with the guidelines.
			1. This policy covers ALL research involving human participants conducted under the auspices of SUNY New Paltz or to be used by current faculty or staff in any professional activity or publication in which the individual claims an affiliation with the institution. This includes both individual and institutional research conducted on or off campus, whether externally funded or not.
			2. The University is considered engaged in a human participants research project when its students, faculty, staff, affiliate researchers or agents for the purposes of the research project obtain: (1) data about the participants of the research through intervention or interaction with them; (2) identifiable private information about the participants of the research; or (3) the informed consent of human participants for the research. For more on the issue of researcher engagement and non-engagement, please see the guidance document titled: [NP SOP 2019 Engagement in Research](https://www.newpaltz.edu/media/sponsored-programs/NP%20SOP%202019%20Engagement%20in%20Research-1.pdf).
			3. It is the policy of SUNY New Paltz that responsibility for review of all research involving human participants lies with the HREB. The HREB has the responsibility and authority to review, prospectively approve, disapprove, grant exemptions for (45 CFR 46.104), require changes in and exercise continuing oversight of research activities involving human participants. No individual involved in the conduct and/or supervision of a specific project shall participate in HREB review, except to provide information.
			4. SUNY New Paltz will provide the HREB with resources, professional staff and support staff sufficient to carry out its responsibilities efficiently and effectively.
			5. Researchers conducting activities involving humans as research participants must provide for the safety, health, and welfare of every individual. Rights, including the right to privacy, must not be infringed upon. No participant in a research activity shall be exposed to unreasonable risk to health or well-being.
			6. An individual does not abdicate any rights by consenting to be a research participant. A participant has the right to withdraw from engagement in a research project at any time or can refuse to participate without loss of benefits to which the participant would otherwise be entitled. Further, a participant has the right to receive appropriate professional care, to enjoy privacy and confidentiality in the use of personal information, and to be free from undue embarrassment, discomfort, anxiety, and harassment.
			7. The direct or potential benefits to the participant, or the importance of the knowledge to be gained, must not preclude consideration of the inherent risks to the individual.
			8. The confidentiality of information received from participants in experiments or respondents to questionnaires shall be fully protected, both during and after the conduct of a research activity, within the limits of the law.
			9. Participation in projects must be voluntary. Written informed consent, as required, must be obtained from all participants, unless this requirement is specifically waived by the HREB in accordance with the requirements of §46.116(a)(4). In research involving more than minimal risk or substantial stress or discomfort, such risk, stress, or discomfort shall be carefully explained to the participant before their participation. The investigator shall be satisfied that the explanation has been understood by the participant. Written consent of the participant must be kept as a matter of record for a minimum of three years following the completion of the study.
			10. Consent should be obtained whenever possible from the participants themselves. In research involving participants with diminished decision-making capacity, a legally authorized representative may be used in the consent process in accordance with the policy in CFR 46 204 Part III, E1.
			11. SUNY New Paltz requires more stringent safeguards for certain research activities and for participants likely to be vulnerable to coercion or undue influence such as:
				1. pregnant women
				2. prisoners
				3. children
				4. persons with physical or mental disabilities
				5. economically or educationally disadvantaged persons
				6. other potentially vulnerable groups
				7. activities involving fetuses and human invitro fertilization, and
				8. activities involving cooperative research projects.
			12. Safeguarding the well-being of and information about an individual is a primary responsibility of the investigator. When the investigator is a student, responsibility for the conduct of the research and the supervision of human participants lies with both the student and the faculty sponsor.
			13. SUNY New Paltz requires that all institutions and investigators (including subcontractors and subgrantees) collaborating in all non-exempt human subjects research operate under an OHRP-approved Federal Wide Assurance for Human Subjects.
			14. SUNY New Paltz will exercise appropriate administrative overview to ensure that practices and procedures designed for the protection of the rights and welfare of human participants are being brought into effect and are in compliance with the federal requirements and this policy. A copy of this policy will be posted on the SUNY New Paltz Office of Sponsored Programs and Research Compliance website and will be sent to faculty/staff requesting copies.
			15. SUNY New Paltz encourages and promotes constructive communication among research investigators, the HREB, SUNY New Paltz administration, and human participants as a means of maintaining a high level of awareness regarding the safeguarding of the rights and welfare of the participants.
			16. No involvement of participants in human participants research is permitted until the HREB has reviewed and approved. It is the responsibility of the investigator to obtain clearance from the HREB prior to the initiation of any human subjects research.
	4. Electronic Management System -- the SUNY Pre Award and Compliance System (PACS)
		1. The University uses an electronic management system for administration and management of the HREB. This system provides electronic management of protocols and documents; online submissions; web-based protocol sharing and collaboration; automatic notifications; the furnishing of electronic signatures; event tracking; and other important electronic features. The University began requiring electronic protocol submissions effective October 2017. All protocols, including revisions and renewals, must be submitted electronically via the electronic management system, and all review decision notifications are issued electronically via the electronic management system. Instructions for the use of this system are located on the HREB website.
	5. Regulatory Compliance
		1. The HREB facilitates compliance with federal regulations, state, and local law and organizational policies. Human subjects research at SUNY New Paltz is conducted in accordance with applicable regulations and requirements including, but not limited to, the following:
			1. Research conducted, supported, or otherwise subject to regulation by any [federal department](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html) [or agency](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html) which adopts the [Common Rule](http://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html) is reviewed and conducted in accordance with the Common Rule. Although the Common Rule is codified by each agency separately, the text is identical to DHHS regulations in [45 CFR 46 Subpart A](http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html). For the purposes of this document, references to the Common Rule will cite the DHHS regulations (45 CFR 46).
			2. The University has opted to apply the Common Rule to all of its human subject research regardless of the source of support.
		2. Studies approved prior to January 21, 2019, where enrollment is permanently closed and only follow-up or collection of standard care data continues, and studies reviewed under expedited procedures may be transitioned to the new Common Rule on a case-by-case basis at the time of continuing review. All other studies approved prior to January 21, 2019, will continue to follow the pre 2018 Common Rule.
	6. Federalwide Assurance (FWA) and HREB Registration
		1. The federal regulations require that federally funded human subjects research only be conducted at facilities covered by an FWA approved by the DHHS Office for Human Research Protections (OHRP). An FWA is an institution’s assurance to the federal government that human subject research conducted at that site is in compliance with federal regulations pertaining to the protection of human participants. The FWA designates the Institutional Review Board(s) (IRB(s)) that will review and oversee the research, specifies the ethical principles under which the research will be conducted, and names the individuals who will be responsible for the proper conduct of the research.
		2. The University has an OHRP-approved FWA (and provides support to one on-site IRB).

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| SUNY New Paltz’s Federal Registration Numbers |
| FWA | **FWA00000127** |
| IRB Registration | **IRB00000992** |

* + 1. The HREB has an attestation (Under NYS Public Health Law, Article 24-A, Section 2445) with New York State that the OHRP-approved FWA takes precedence over relevant New York State laws.
	1. SUNY New Paltz’s HREB covers all research involving human participants that is under the auspices of the University. The research may be externally funded, funded from internal University sources, or conducted without direct funding.
	2. Written Procedures
		1. These Standard Operating Procedures (SOPs) for Human Research Protection detail the procedures, standards, and requirements for research with human participants under the auspices of SUNY New Paltz and the requirements of the SUNY New Paltz HREB. This is not a static document. The SOPs are reviewed annually and revised, as needed, by the HREB.
		2. The HREB Chair will keep the research community apprised of new information that may affect human subjects research, including laws, regulations, policies, procedures, and emerging ethical and scientific issues on the HREB website, through email, and other forums. All SOPs will be available on the HREB website and within the SUNY Pre-Award and Compliance System (PACS).
	3. Changes to SOPs are communicated to investigators through email.
1. SUNY New Paltz HREB Structure and Responsibilities
	* 1. Institutional Official
			1. The ultimate responsibility of the Human Research Protections Program (HRPP) resides with the Institutional Official (IO). The IO is legally authorized to represent SUNY New Paltz. The IO is the signatory of the FWA and assumes the obligations of the FWA. At SUNY New Paltz, the IO is the Provost or their designee.
			2. The IO is responsible for ensuring that the HREB has the resources and support necessary to fulfill their responsibilities and comply with the regulations and requirements that govern human subject research.
			3. The IO signs the attestation under NYS PHL 24-A and submits it.
		2. Assistant Vice President of Sponsored Programs & Research Compliance
			1. The AVP of Sponsored Programs & Research Compliance serves as the Director of the HRPP, reports to the IO, and is responsible for:
				1. Advising the IO on key matters regarding human subjects research.
				2. Implementing the HREB’s SOPs;
				3. Overseeing the administration of the HRPP and HREB, including the supervision of staff;
				4. Submitting, implementing and maintaining an approved FWA through the IO and the Office of Human Research Protection (OHRP) at the Department of Health and Human Services;
				5. Managing the finances of the University HREB;
				6. Serving as the primary contact at the University for the OHRP, the Food & Drug Administration (FDA), and other regulatory agencies on matters of human research protections; Serving as an internal expert resource for questions and other matters regarding the protection of human participants.
				7. Negotiating and updating the terms of the Memorandum of Understanding (MOU) with SUNY System Admin (SSA) and Rockefeller Institute of Government (RIG).
		3. Human Protections Administrator
			1. The AVP of Sponsored Programs & Research Compliance or the Institutional Signatory’s designee serves as the campus Human Protections Administrator unless another acceptable provision has been made.
			2. Duties of the HPA
				1. Developing, managing and evaluating policies and procedures that ensure compliance with state and federal regulations and University policies in conjunction with the HREB and HREB Chair.
				2. Monitoring changes in regulations and policies that relate to human research protection and ensuring the HREB is notified of changes to federal requirements that impact human subjects research.
				3. Overseeing the administration of the HREB;
				4. Managing IRB Authorization Agreements and Independent Investigator Agreements;
				5. Managing MOU with RIG and SSA Assisting the HREB in its efforts to review research and ensure the protection of human participants.
				6. Assisting investigators in their efforts to carry out the organization’s research mission;
				7. Developing and implementing needed improvements and ensuring follow-up actions, as appropriate, for the purpose of managing risk in the research program.
				8. Providing guidance to the HREB chair.
		4. HREB Coordinator
			1. Ensures that all investigators have completed CITI training.
			2. Maintains the HREB website by keeping documents up-to-date and accessible.
			3. Bills Rockefeller Institute of Government (RIG) and SUNY System Administration.
			4. Sets up HREB meetings and takes minutes
			5. Manages the SUNY Pre-Award and Compliance System (PACS) including:
				1. Overseeing the creation of PACS accounts.
				2. Conducting prereviews to ensure all documents are ready for review.
				3. Assigning prereviews to faculty mentors and ensuring faculty assurance documents are uploaded.
				4. Assigning reviews to HREB members.
				5. Finalizing approval letters.
				6. Providing end user support for investigators and HREB members.
				7. Maintaining PACS Library.
			6. Completes the NYS attestation under NYS PHL 24-A form and sends to the signatory official for signature and submission.
		5. HREB Board Members
			1. HREB members prospectively review and make decisions concerning exempt and non-exempt human subjects research conducted under the auspices of the University.
			2. HREB members engage in ongoing continuing education related to human subjects research ethics and oversight.
			3. HREB members assist in the regular review, revision, creation, and approval of HREB policies and procedures.
			4. HREB members consider and make determinations regarding potential instances of non-compliance.
			5. HREB members serve as a resource on human subjects research and HREB policies and procedures to the University community.
			6. HREB members attend HREB meetings.
			7. Conflicts of Interests
				1. No HREB member, alternate member, or consultant may participate in the review (initial, continuing, or modification) of any research project in which the individual has a conflict of interest (COI), except to provide information as requested.
				2. HREB members, alternate members, or consultants must disclose any COI in a study submitted for review and then recuse themself. At convened meetings, the HREB member, alternate member, or consultant will recuse themselves from the deliberations and vote by leaving the room.
				3. Common COIs

HREB member or consultant is involved in the design, conduct, or reporting of the research.

Where an immediate family member of the HREB member or consultant is involved in the design, conduct, and reporting of the research.

Where the HREB member holds significant financial interests related to the research being reviewed.

Any other situation where an HREB member believes that another interest conflicts with their ability to deliberate objectively about a protocol.

* + - * 1. If the COI status of an HREB member changes during the course of a study, the HREB member is required to complete an amended “HREB Member Human Research Conflict of Interest Assessment Form” and submit the completed document to the HPA, who will, in turn advise the HREB Coordinator and HREB Chair of the change.
		1. HREB Chair
			1. Works with the HPA and IO to recruit new HREB members.
			2. Oversees the review of all Human Subjects Research.
			3. Mentors and trains HREB members.
				1. Oversees the training of new HREB members.
				2. Ensures the continuing education of all HREB members.
				3. Provides support to HREB members conducting reviews.
			4. Oversees Exempt Reviewer Training.
			5. Ensures the continuing education of all campus constituents.
			6. Calls regular and special meetings of the HREB.
			7. Oversees the HREB’s assessment function.
			8. Manages the annual audit.
			9. Conducts ongoing reviews:
				1. Non-human Subjects Determinations.
				2. Modifications to existing protocols.
				3. Continuing review of existing protocols.
		2. HREB Associate Chair
			1. Works with HREB Chair to ensure the ethical oversight of human subjects research.
			2. Assists in the annual audit.
			3. Reviews non-human subjects determinations, modifications to existing protocols, and continuing review of existing protocols for studies conducted by the HREB Chair.
			4. The Associate Chair must have the ability to step into the role of the HREB Chair if the HREB Chair is unable perform those functions.
		3. Principal Investigators
			1. The Principal Investigator (PI) is ultimately responsible for the protection of the human participants in research they conduct or oversee.
			2. The PI is expected to abide by the highest ethical standards when developing a research plan and to incorporate the principles of the [Belmont Report](https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html).
			3. The PI is expected to conduct research in accordance with the HREB approved research plan and to personally conduct or oversee all aspects of the research. In addition to complying with all applicable regulatory policies and standards, PIs must comply with organizational and administrative requirements for conducting research.
			4. The PI is responsible for ensuring that all investigators and research staff complete all University-required trainings and maintain certification, as well as training for their specific responsibilities in any given research study.
			5. If a study will be ongoing while a PI is on a planned extended absence (e.g., sabbatical), the PI must find a replacement PI for that project to continue. If a study lead by a student PI will be ongoing while a Faculty Advisor is on a planned extended absence, the Faculty Advisor must find a replacement PI for the project to continue. For unplanned absences, the HREB Chair and IO will consult with relevant Deans and/or Chairs on an appropriate replacement.
			6. The PI for human participants research under the auspices of the University must be an active member of the campus community (i.e., faculty, staff, students).
				1. For information on the HREB and Adjuncts, please read the [Adjunct Faculty Policy for Human Participants Research Policy](https://www.newpaltz.edu/media/sponsored-programs/NP%20SOP%202019%20Adjunct%20Faculty%20Policy%20for%20Human%20Subjects%20Research.pdf).
			7. Special Considerations:
				1. Individuals who are debarred, disqualified, or otherwise restricted from participation in research or as a recipient of grant funds for research by a federal, state, or other agency may not serve as PI.
				2. Individuals with a history of compliance issues related to the conduct of research will be considered on a case-by-case basis.

Factors to consider include whether corrective actions have been accepted as adequate, whether information from an audit or quality review indicates that the issues have been resolved, and similar considerations.

Non-compliant researchers may have a research protocol suspended or terminated as per the Noncompliance Policy.

1. Education & Training
	1. HREB Member Training / Continuing Education of HREB Chair, Members, and Staff
		1. HREB Member Onboarding
			1. All HREB members will go through a rigorous onboarding process prior to becoming a voting member of the HREB.
			2. The Chair of the HREB (or their designee) oversees the onboarding process of all new HREB members.
		2. Continuing Education
			1. To ensure that oversight of human research is ethically grounded, and the decisions made by the HREB are consistent with current regulatory and policy requirements, training is continuous for HREB members throughout their service on the HREB. Educational activities include, but are not limited to:
				1. In-service training at HREB meetings;
				2. Webinars;
				3. Copies of appropriate publications and articles;
				4. Identification and dissemination by the HREB Chair or HPA of new information that might have an effect on the human research protection program, including laws, regulations, policies, procedures, and emerging ethical and scientific issues to HREB members via email, mail, or during HREB meetings.
				5. Attending Public Responsibility in Medicine and Research (PRIM&R) Convention at least once during their term on the HREB (if possible).
		3. The HREB will endeavor to ensure that it is provided with resources, professional staff, and support staff appropriate to the nature and volume of the research for which it is responsible.
		4. The HREB Chair will meet with the Provost at least annually to discuss resource, training needs, and staff allocation requirements.
	2. Training / Ongoing Education of Investigators and Research Team
		1. The HREB will require human protections education of research investigators, HREB members, and other relevant personnel.
		2. The HREB will require documentation of such training from research investigators as a condition for conducting human participant research.
		3. Initial Education
			1. All individuals involved with human participants research (e.g., principal investigators, research team members, student researchers, faculty members overseeing research, etc.) must complete the [Collaborative IRB Training Initiative](https://www.citiprogram.org) (CITI) basic course.
			2. Instructions for registering and completing the CITI Basic Course can be found on the [HREB Website](https://www.newpaltz.edu/sponsored_programs/citi.html).
		4. Continuing Education
			1. Investigator Training and Research Team
				1. The HREB will provide ongoing training for research personnel (including principal investigators, research team members, student researchers, faculty members overseeing research, etc.) on campus.
				2. All individuals engaged in research must complete the CITI refresher course every five years.
2. Human Research Ethics Board
	1. HREB Functions
		1. The HREB shall follow written policies and procedures of the State University of New York at New Paltz for the protection of human research participants which are in compliance with applicable Federal law and applicable New York State law (Laws of New York 1975, Chapter 450, Article 24-A, Protection of Human Participants). .
		2. The HREB is responsible for ensuring compliance with federal regulations, state law and institutional policies (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe). All human participants research at the University is conducted in accordance with the policy and regulations found in the Common Rule and 21 CFR 50 and 56. Regulatory compliance for research funded by other federal agencies (e.g., Department of Defense, Department of Energy, Department of Education etc.) will be addressed as needed. The University applies the International Conference on Harmonization ("ICH") to research when required by a sponsor, and only to the extent that they are compatible with FDA and DHHS regulations. The university applies the guidelines of the European Union's General Data Protection Regulation (GDPR), when appropriate.
		3. The actions of the University will also conform to all other applicable federal, state, and local laws and regulations.
		4. SUNY New Paltz meets the exemption from NYS law pertaining to research with human participants
		5. Except when an exempt or expedited review procedure is applicable, the HREB shall review proposed research at convened meetings at which a majority of the members of the HREB are present, including at least one member whose primary concerns are in non-scientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.
		6. A convened meeting may either take place with members present in one location or may be conducted via telephone conference call provided that each participating HREB member:
			1. Has received all pertinent material prior to the meeting, and
			2. Can actively and equally participate in the discussion of all protocols. Minutes of such meetings must clearly document that these two conditions have been satisfied in addition to the usual regulatory requirements (e.g., attendance, initial and continued presence of a majority of members, including at least one nonscientist member; actions taken by the HREB; the vote on such actions; discussion and resolution of controverted issues).
	2. HREB and the Review of Research
		1. The HREB shall have the responsibility to review and the authority to approve, require modifications in (to secure approval), or disapprove all research activities or proposed changes in previously approved activities covered by this policy.
		2. The HREB shall require that information given to participants as part of informed consent is in accordance with 46.116. The HREB may require that information, in addition to that specifically mentioned in 46.116, be given to the participants when in the HREB's judgment the information would meaningfully add to the protection of the rights and welfare of participants.
		3. The HREB shall require documentation of informed consent or may waive documentation in accordance with **§46.116(a)(4)**.
		4. The HREB shall notify investigators and the institution (the Provost/Vice President for Academic Affairs) in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure HREB approval of research activity. If the HREB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.
		5. The HREB shall conduct continuing review of research when deemed necessary intervals appropriate to the degree of risk, but not less than once per year. Based on the degree of risk to human participants, the Board may grant special conditions whereby the investigator has a shorter approval period or must report research progress at specific intervals. The HREB shall have authority to observe or have a third party observe the consent process and research activities.
		6. All research approved under Expedited or Full-Board procedures will be assessed annually through an administrative check-in.
		7. All research reviewed by the HREB is conducted in accordance with 45 CFR 46 (The Common Rule). Research falls into one of three levels of review: exempt, expedited, and full board.
			1. [NP SOP 2019 Exempt Categories](https://www.newpaltz.edu/media/sponsored-programs/NP%20SOP%202019%20Exempt%20Categories.docx)
			2. [NP SOP 2019 Expedited Categories](https://www.newpaltz.edu/media/sponsored-programs/NP%20SOP%202019%20Expedited%20Categories.pdf)
			3. Full Board Review
				1. Human participants research that is not Exempt or eligible for Expedited Review must be reviewed at a convened meeting of the HREB.
				2. Full board review usually involves research that is greater than minimal risk but also includes minimal risk research that does not meet one or more of the Expedited Review Categories.
				3. If the full board determines that the research is indeed minimal risk, then all subsequent reviews may use Expedited Review procedures.
	3. Roles and Responsibilities
		1. HREB Chair
			1. The University’s Institutional Official appoints the HREB Chair. Any change in appointment, including reappointment or removal, requires written notification.
			2. Qualifications
				1. The HREB Chair should be a highly respected individual, from within the University, and fully capable of managing the HREB (and the matters brought before it) with fairness and impartiality.
				2. HREB Chairs are primarily responsible for ensuring that the HREB is fair, impartial and immune to pressure by the University’s administration, the investigators whose protocols/studies are brought before the HREB, and other professional and nonprofessional sources.
			3. Duties
				1. The HREB Chair is responsible for calling and conducting HREB meetings.
				2. The HREB Chair delegates to the HREB Coordinator and HREB Members the responsibility of being signatory for correspondence generated by the HREB.
				3. The HREB Chair also oversees:

Modifications of Protocols

Continuing Approval of Protocols

Non-Human Participants Determinations

Coordinating the Annual Audit

* + - 1. Removal of an HREB Chair
				1. If an HREB Chair is not acting in accordance with the HREB’s mission, following national and state law, following these policies and procedures, has an undue number of absences, or not fulfilling the responsibilities of the HREB Chair, they will be removed.
				2. Removal of an HREB Chair is never to be taken lightly. The removal of an HREB Chair must be done through a consultative process involving the HREB, the HPA, and the Institutional Signatory.
		1. Associate Chair of the HREB
			1. The University’s Institutional Official in conjunction with the HREB Chair and HPA appoints the Associate Chair of the HREB.
			2. Qualifications
				1. The HREB Associate Chair should be a highly respected individual, from within the University, fully capable of managing the HREB (if need be), and the matters brought before it with fairness and impartiality.
				2. HREB Associate Chair helps ensure that the HREB is fair, impartial, and immune to pressure by the University’s administration, the investigators whose protocols/studies are brought before the HREB, and other professional and nonprofessional sources.
				3. The HREB Associate Chair can function as a temporary and/or interim HREB Chair if the HREB Chair is unavailable (e.g., sabbatical, illness, vacation, etc.).
			3. Duties
				1. The HREB Associate Chair is an important sounding board for the HREB and the HPA.
				2. The HREB Associate Chair also oversees:

Modifications of Protocols conducted by the HREB Chair

Continuing Approval of Protocols conducted by the HREB Chair

Non-Human Participants Determinations for protocols presented by the HREB Chair

Help in conducting the Annual Audit

* + - 1. Removal of an HREB Associate Chair
				1. If an HREB Associate Chair is not acting in accordance with the HREB’s mission, following national and state law, following these policies and procedures, has an undue number of absences, or not fulfilling the responsibilities of the HREB Associate Chair, they will be removed.
				2. Removal of an HREB Associate Chair is never to be taken lightly. The removal of an HREB Associate Chair must be done through a consultative process involving the HREB Chair, the HPA, and the Institutional Signatory.
		1. HREB Members
			1. Any School on campus that conducts human participants research shall have at least one member on the HREB (e.g., School of Business, School of Education, School of Fine and Performing Arts, and School of Liberal Arts and Sciences, and School of Science & Engineering).
			2. All HREB members must possess the professional competence necessary to review specific research activities.
			3. HREB members must be able to ascertain the acceptability of proposed research in terms of the University policies and regulations, applicable law, and standards of professional conduct and practice.
			4. The HREB will have at least five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the University.
			5. Diversity on the HREB
				1. Every nondiscriminatory effort will be made to ensure that the membership is diverse. Potential members of the HREB will not be discriminated against because of race, color, religion, sex (including pregnancy, sexual orientation, or gender identity), national origin, age (40 or older), disability, and genetic information (including family medical history).
				2. The HREB will include members who are knowledgeable about and experienced working with participants vulnerable to coercion or undue influence (e.g., children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons) that are regularly included in the research under its review.
				3. The HREB shall include at least one scientific and one non-scientific member.
				4. The HREB will include at least one member who is not otherwise affiliated with the University and who is not part of the immediate family of a person who is affiliated with the University.
			6. Appointment
				1. The HREB Chair, Associate Chair, HPA, HREB membership, or IO can identify the need for a new or replacement member, or alternate member.
				2. When there is not an immediate replacement from a School with current vacancy on the HREB, the HREB will work in conjunction with that School’s Dean, the HPA, and the IO to identify an appropriate replacement.
				3. Upon recommendations from the HREB, the University’s Institutional Official appoints all HREB members for a 3-year term.
				4. On an annual basis, the HREB Chair, HREB Coordinator, and the HPA (on behalf of the IO) review the membership and composition of the HREB to ensure they continue to meet regulatory and institutional requirements.
				5. If a School is not represented on the HREB for more than one academic semester (not including the summer), the HREB Chair (in consultation with the HPA and IO) may decide to not accept new research protocols from that School until an appropriate replacement is identified.
			7. Duties of HREB Members
				1. HREB members will treat the research proposals, protocols, and supporting data confidentially.
				2. Meeting Attendance

HREB members should attend all meetings for which they are scheduled. If an HREB member is unable to attend a scheduled meeting, they should inform the HREB Coordinator and the HREB Chair as soon as possible.

HREB members should be prepared to discuss all materials distributed prior to an HREB meeting.

If an HREB member is to be absent for an extended period of time, such as for a sabbatical, he or she must notify the HREB Coordinator and HREB Chair at least 30 days in advance so that the HREB can find a possible replacement if it is determined to be necessary.

* + 1. Alternate HREB Members
			1. Although not required, the HREB may have alternate members to ensure that a quorum is met.
			2. Alternate HREB members will go through the same onboarding process as regular members, but they will not be expected to attend every HREB meeting.
	1. Liability Coverage for HREB Members
		1. The on-site HREB is constituted by the State University of New York (SUNY). NYS Public Officers Law, section 17 provides that where the requirements of Public Officers Law, section 17 are met, and contingent on a determination by the Attorney General of the State of New York, the state shall provide for the defense of state employees and officers in civil action or proceeding in any state or Federal court arising out of the any alleged act or omission which occurred or is said to have occurred while the state employee or officer was acting within the scope of his/her public employment or duties carried out on behalf of the state.
	2. Use of Consultants
		1. When necessary, the HREB may solicit individuals from within or outside The University competent in special areas to assist in the review of issues or protocols, which require appropriate scientific or scholarly expertise beyond (or in addition to) that available on the HREB.
		2. The need for a consultant may be determined in advance of, or during the review of the study at, an HREB meeting. The HREB Coordinator ensures that all relevant materials are provided to the consultant in a timely manner following determination that an outside review is required.
		3. When the convened HREB requires consultation by individuals with appropriate expertise, the study will be tabled and reviewed at the next convened HREB meeting.
		4. Written statements of consultants will be kept in HREB records. Key information provided by consultants at meetings will be documented in the minutes. Written reviews provided by outside reviewers and consultants will be filed with the study.
		5. Ad hoc or informal consultations requested by individual HREB members (rather than the full board) will be requested in a manner that protects the investigator’s confidentiality in compliance with the HREB conflict of interest policy.
1. HREB Actions, Failure to Respond, Appeals
	1. HREB Actions
		1. The HREB may take any of the following actions. With the exception of disapproval, the actions listed below may be used for exempt, expedited, or full board review:
			1. Approval: The study is approved as submitted.
			2. Modifications Required
				1. Changes to a PI’s protocol may be required by individual HREB members reviewing a protocol or by a convened meeting of the HREB.
				2. Requested revisions are prescriptive, requiring concurrence by the PI (e.g., the submission requires minor revisions such as wording changes with suggested replacement language provided, or confirmation by the PI of the HREB’s understanding of a particular issue).
				3. All required modifications are communicated to the investigator in writing and documented in PACS.
				4. For studies undergoing review by the board, the requested revisions are agreed upon at the meeting.
				5. These deliberations are documented in the minutes which are uploaded into PACS.
				6. For studies brought to the board, the HREB may recommend bringing revisions back to the Full Board or allowing the HREB Chair or Associate Chair to approve the protocol pending the agreed upon changes.
				7. Approval of the protocol application will not be granted until all prescribed protocol changes are corrected to the satisfaction of the final reviewer(s).
			3. Deferral (Exempt/Expedited Review)
				1. Any HREB reviewer can defer making a decision on an HREB protocol until after the reviewer has brought up any questions or concerns about a protocol with the Full HREB Board.
				2. At every meeting, there will be an open period where HREB members will openly discuss pending protocols.
				3. During these HREB discussions, the HREB can recommend the individual reviewer complete the review after the discussion, refer the review to the HREB Chair (or designee), or refer the review to the Full HREB.
		2. Tabling of a Protocol
			1. During a meeting of the Full Board, a protocol may be tabled pending further information or clarification from the PI, discussion with an external consultant, completion of all protocol forms, etc.
			2. Tabling may occur when the HREB is unable to review the research at the convened meeting (e.g., due to incomplete submission, loss of quorum, etc.).
		3. Disapproval of a Protocol
			1. A recommendation of disapproval can only be taken at a convened HREB meeting.
			2. A recommendation of disapproval can be made when the HREB has determined that the research cannot be conducted at The University or by employees or agents of The University or otherwise under the auspices of The University.
			3. Recommendations of disapprovals must be determined at meetings of the full committee; they cannot be determined at the level of exempt or expedited review.
			4. Disapproval Process
				1. The full HREB will convene and vote to recommend disapproving the protocol.
				2. The vote and justification will be communicated to the Human Protections Administrator who can agree with the HREB or recommend the HREB revisit the protocol at their next meeting.
				3. If the HPA agrees with the disapproval recommendation, the recommendation of the HREB, their vote/justification, and the HPA’s concurrence will be forwarded to the Campus Signatory Official.
				4. Only the Campus Signatory Official can disapprove a study protocol. Upon receiving a disapproval recommendation, the signatory official can:

Agree with the findings of the HREB and HPA and disapprove the protocol.

Disagree with the findings of the HREB and the HPA and approve the protocol.

Ask that the HPA and the HREB reexamine the protocol after their investigation.

* 1. Failure to Respond
		1. Upon review of a research protocol or modification, the HREB may require changes or request certain information from the PI.
		2. Failure to respond to HREB required changes or requests for information may result in suspension or termination of HREB approval for the study.
		3. For studies that have not yet been approved, the study submission may be administratively withdrawn after 90 Days.
	2. Reporting HREB Actions
		1. All HREB actions are communicated to the PI in writing via the HREB electronic system (PACS) within ten (10) working days, whenever possible, of the action.
		2. All HREB actions are recorded in the minutes of the HREB board.
	3. Appeal of HREB Decisions
		1. Investigators may appeal:
			1. Revisions required by the HREB;
			2. HREB determinations of non-compliance, serious non-compliance, continuing non-compliance, 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
		2. 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.
		3. See Appeals Policy
1. HREB Review Process
	1. Electronic Management System -- the SUNY Pre Award and Compliance System (PACS)
		1. The University uses an electronic management system for administration and management of its HREB. Thissystem provides electronic management of protocols and documents; on-linesubmissions; web-based protocol sharing and collaboration; automatic notifications; thefurnishing of electronic signatures; event tracking; and other important electronicfeatures. The University began requiring electronic protocol submissions effective **October 14, 2017,** All protocols, including revisions and renewals, must be submitted electronically via theelectronic management system, and all review decision notifications are issued electronicallyvia the electronic management system. Instructions for the use of this system are located onthe HREB website.
	2. Convened HREB Meetings
		1. HREB Meeting Schedule
			1. The HREB meets bi-weekly throughout the year (and three times during the summer). The meeting schedule for the HREB may vary due to holidays or lack of quorum.
			2. The schedule of meeting deadlines and meeting dates is available on the [HREB website](https://www.newpaltz.edu/sponsored_programs/humansubs.html).
			3. Special meetings can be called at any time by the HREB Chair, the HPA, or the IO.
		2. Preliminary Review
			1. The HREB Coordinator will perform a preliminary review of all study materials submitted for HREB review for determination of completeness, accuracy, special regulatory considerations, CITI training of all researchers, applicable ancillary reviews, etc.
			2. Only complete submissions will be sent to the HREB for review.
			3. The HREB Coordinator will notify the principal investigator of missing information through the PACS electronic management system.
		3. Primary Reviewers
			1. After it has been determined that the research study submission is complete, the HREB Coordinator will assign the research study to reviewer(s).
			2. When the HREB is presented with a protocol that may be outside of the knowledge base of any of the IRB members, consultation with an outside knowledgeable source will occur.
		4. Materials for Full Board Reviews and Discussions
			1. Pre-Meeting Distribution of Documents
			2. The study, including all required materials, needs to be submitted at least seven days prior to a particular meeting for inclusion on the HREB agenda.
			3. The meeting agenda will be prepared by the HREB Chair and made available to HREB members prior to the meeting.
			4. All HREB members should receive access to the protocol to be reviewed in the electronic management system, no later than five (5) business days before the scheduled meeting to allow sufficient time for the review process.
			5. Prior month’s meeting minutes, applicable business items and audits, and appropriate continuing education materials will be made available to the members as far in advance of the meeting as possible.
		5. Quorum
			1. A quorum consists of a simple majority (more than half) of the voting membership, including at least one member whose primary concern is in a non-scientific area.
				1. The HREB Chair, with the assistance of the HREB Coordinator, will confirm that an appropriate quorum is present before calling the meeting to order.
				2. The HREB staff will be responsible for ensuring that the meetings remain appropriately convened.
				3. A quorum must be maintained for each vote to occur.
				4. The HREB staff takes note of arrivals and departures of all members and notifies the chair if a quorum is not present.
				5. If a quorum is not maintained for reasons relating to an HREB member’s recusal due to a Conflict of Interest, the individual proposal must be tabled. If quorum is lost for the remaining duration of the meeting, the meeting must therefore be terminated.
			2. In the case of prisoner research, a quorum cannot be made without the prisoner advocate present.
			3. HREB members are considered present if participating through teleconference or videoconference.
			4. Opinions of absent HREB members that are transmitted by mail, telephone, facsimile, or e-mail may be considered by the attending HREB members but may not be counted as votes or to satisfy the quorum for convened meetings.
		6. Meeting Procedures
			1. The HREB Chair will call the meeting to order, once it has been determined that a quorum is in place.
			2. The HREB will review and approve the agenda for the meeting.
			3. Review of Minutes
				1. The HREB will review and discuss the minutes from the prior meeting and determine if there are any revisions/corrections to be made.
				2. If there are no changes to be made, the minutes will be accepted as presented and considered final.
				3. If major revisions/corrections are necessary, the minutes will be amended and approved as amended.
				4. If substantial revisions are necessary, the HREB can table the minutes and reevaluate them after they’ve been amended at the next meeting.
			4. If there are any full board reviews, the HREB will take up these reviews.
			5. Any cases of Noncompliance will be discussed.
			6. A discussion of the current list of HREB activity will occur.
			7. Discussion of Review Issues
				1. HREB members are encouraged to discuss any protocols they are currently reviewing.
				2. This informal feedback will help the individual HREB members in their decision-making process.
				3. If the HREB finds a protocol needing further analysis, the protocol can be referred to the Chair, Associate Chair, or the Full Board.
			8. The HREB Board will discuss any agenda items under Other Business currently set.
			9. The HREB Board will adjourn.
				1. The HREB will adjourn under three circumstances:

The HREB no longer has quorum.

The HREB meets its time limit for the meeting and HREB members cannot stay longer.

The HREB concludes its business.

* + - * 1. A motion for adjournment must be moved, seconded, and approved by the HREB.
		1. Guests
			1. Investigators and research staff may be invited to the HREB meeting, at the discretion of the HREB, to make a brief presentation or answer questions about proposed or ongoing research.
			2. The investigator/research staff may not be present for the deliberations or vote on the research.
			3. Other guests may be permitted to attend HREB meetings at the discretion of the HREB Chair and the HPA.
				1. Such guests do not participate in discussion unless requested by the HREB.
				2. Under no circumstances may guests vote, and they will be reminded that all discussions and deliberations are confidential.
	1. Criteria for HREB Approval of Research
		1. For the HREB to approve human participants research, either through expedited review or by the convened HREB, it must determine that the following requirements are, or remain, satisfied.
			1. Where the risk is deemed more than minimal, judge whether the anticipated benefit justifies asking any person to undertake the risks.
			2. Avoid approving research where the risks outweigh the proposed benefits.
			3. Ensure that all three of the criteria presented in the [Belmont Report](https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html) (respect for persons, beneficence, and justice) are met by ensuring informed consent, equitable selection of participants, and an appropriate risk/benefit assessment.
			4. Additional considerations when approving research include scientific merit, data and safety monitoring, privacy and confidentiality, and the use of vulnerable populations.
		2. Informed Consent
			1. Informed consent will be sought from each prospective participant or the participant's legally authorized representative, in accordance with, and to the extent required by the Federal Regulations [[45 CFR 46.116](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.116)/[21 CFR 50](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50)].
			2. Informed consent will be appropriately documented, in accordance with, and to the extent required by the Federal Regulations [[45 CFR 46.117](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.117)/[21 CFR 50](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50)].
			3. The HREB will ensure that the consent document reflects the information in the protocol.
		3. Equitable Selection of Participants
			1. The HREB evaluates whether the selection of participants is equitable with respect to biological sex/gender, age, socioeconomic status, etc.
			2. The HREB will not approve protocols where there is a clear bias in the equitable selection of participants unless there is an appropriate scientific and ethical justification.
		4. Risk/Benefit Assessment
			1. The goal of all HREB reviews is to ensure that the risks associated with participating in the research is balanced by the anticipated benefits to the participants or society.
			2. The risk benefit analysis is based on the following steps:
				1. Identifying possible risks associated with research participation.
				2. Determining whether the PI has minimized those risks.

Risks to participants are minimized (i) by using procedures which are consistent with sound research design, and which do not unnecessarily expose participants to risk, and (ii) whenever appropriate, by using procedures already being performed on the participant for diagnostic or treatment purposes (45 CFR 46.111(a)(1)

Determining if appropriate steps have been taken to ensure the privacy and confidentiality of the participant.

* + - * 1. Identifying anticipated benefits to both the participants and society.
				2. Determining if the risks to the participants are reasonable in relation to the possible benefits.
		1. Scientific Merit
			1. Although the HREB is not the arbiter of what is considered “good” research, the HREB must evaluate the scientific merit of a research protocol when considering expedited and full board protocols to ensure a complete analysis of risks and benefits.
			2. The HREB must consider:
				1. Whether the research is consistent with sound research methods and design.
				2. Whether the design is sound enough to answer the proposed research questions.
				3. Whether the knowledge from the research is sufficient to justify the possible risks to participants.
			3. In determining scientific merit, the HREB can consult numerous sources:
				1. The HREB’s own knowledge and disciplinary expertise.
				2. The knowledge and disciplinary expertise of non-HREB members.
				3. The peer review process of funding agencies.
		2. Data and Safety Monitoring
			1. For all research that is more than minimal risk, the investigator must submit a data safety-monitoring plan.
				1. Monitoring is commensurate with the nature, complexity, size, and risk involved.
				2. Monitoring is timely. Frequency should be commensurate with risk. Conclusions are reported to the HREB.
				3. Continuous, close monitoring by the study investigator or an independent individual may be an adequate and appropriate format for monitoring, with prompt reporting of issues and concerns to the HREB, sponsor and regulatory bodies as appropriate.
			2. For all non-exempt research and exempt research involving non-anonymized data, data security must also be evaluated. This includes assessing the following:
				1. The researcher provided a clear justification for needing identifiers in order to conduct research.
				2. The researcher explained the sensitivity of the data being collected.
				3. The researcher clearly explained how long identifiable data will be retained.
				4. The researcher has adequate security controls for identifiable data (i.e., physical safeguards for paper records or recordings, technical safeguards for electronic records, secure sharing or transfer of data outside the institution, if applicable).
				5. Researcher explained that the potential risk for harm that would occur if the security of the data was compromised is below minimal risk.
		3. Privacy and Confidentiality
			1. The HREB will determine whether adequate procedures are in place to protect the privacy of participants and to maintain the confidentiality of the data.
			2. Privacy is defined as having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.
				1. The HREB must ascertain if the research would constitute an invasion of privacy.
				2. The researcher must provide information regarding how the investigators are getting access to participant private, identifiable information, and the participants’ reasonable expectations of privacy.
				3. Researchers must have appropriate, documented authorization to interact with participants or access participants’ information.
			3. Confidentiality is defined as methods used to ensure that information obtained by investigators about their participants is not improperly divulged.
				1. Confidentiality and anonymity are not the same. If anyone, including the investigator, can readily ascertain the identity of the participants from the data, then the data from the research are not anonymous.
				2. The HREB must determine if appropriate protections are in place to minimize the likelihood that the information will be inappropriately divulged for all non-anonymized data sets.
				3. To ensure confidentiality, the researcher must explain to the HREB the following:

How information about the research participants will be obtained.

How individuals will be recruited to participate in the research.

How personally identifiable records will be used.

The methods the researcher will employ to protect the confidentiality of their participants and the data.

* + 1. Vulnerable Populations
			1. When some or all of the participants in a protocol are likely to be vulnerable to coercion or undue influence (e.g., children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons), the HREB should include additional safeguards to protect the rights and welfare of these participants.
			2. The HREB will consider the scientific and ethical reasons for including vulnerable participants in research.
			3. The HREB may require additional safeguards for vulnerable participants where appropriate.
			4. [45 CFR 46](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML) has additional subparts designed to provide extra protections for vulnerable populations that also have additional requirements for the IRB.
				1. [Subpart B](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#sp45.1.46.b) - Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research
				2. [Subpart C](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#sp45.1.46.c) - Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects
				3. [Subpart D](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#sp45.1.46.d) - Additional Protections for Children Involved as Subjects in Research
	1. Specific Review Procedures
		1. Introduction
			1. The HREB authorizes three (3) levels of review based on the type of research activity. These levels are: (a) full review by the HREB, (b) expedited review by the HREB for research as specified in II, C.3, and (c) HREB certification of exempt status.
			2. All research activity proposals are to be submitted in the PACS electronic management system. The HREB Coordinator will do a preliminary review to determine whether the research protocol meets the criteria for exemption from review, expedited review or full review.
			3. The research investigators shall be notified in writing through PACS of the HREB’s decisions, conditions and requirements.
			4. The HREB shall provide to the investigator reasons for the HREB's decision to disapprove a research protocol and an opportunity for the investigator to respond.
		2. Full Review by Human Research Ethics Board
			1. Full-board review by the HREB is required for all protocols, except those meeting exempt or expedited review criteria. Only in limited cases will research involving vulnerable participants meet the criteria for exempt or expedited review. All prisoner research must be reviewed by the full-board.
			2. All students should first secure written approval from faculty advisor. Forms are available on the Sponsored Programs website.
			3. All applications must be submitted through the PACS electronic management system.
			4. For Full Board Review, applications should be submitted to the PACS system three (3) weeks prior to a regularly scheduled Board meetings. The schedule of HREB meetings is on file in the Office of Sponsored Programs and on the Sponsored Programs website.
			5. Attendance of the investigator at the HREB review meeting in which their research activity is scheduled for discussion is encouraged.
			6. No research involving human participants in any fashion shall be initiated until approval has been given by the HREB.
			7. The formal actions taken by the HREB will consist of:
				1. Approval - indicates the researcher may begin (continue, if request is for continuation of research) data collection and that the project meets the HREB standards for human participant research.
				2. Approval withheld pending revision/external site approval - indicates approval by the HREB has been withheld pending revision of specific points or external site approval. Research may not be undertaken until the outlined revisions/site approval are submitted to and approved by the HREB or designated member.
				3. Resubmission Recommended: Major Revisions Required - indicates approval by the HREB has been withheld as the proposed research does not meet SUNY New Paltz and federal guidelines for the protection of human participants. The research activity may not be undertaken, and will not be endorsed by the institution, unless the investigator significantly revises the original application.
				4. Disapproval - indicates the proposed research does not meet SUNY New Paltz and federal guidelines for the protection of human participants. The research activity may not be undertaken and will not be afforded institutional endorsement. The investigator shall have the opportunity to respond in-person or in writing to the HREB.
			8. Approval of proposed research is usually granted for a period of 12 months commencing on the date approval is granted by the Board at a convened meeting. Based on the degree of risk to human participants, the Board may grant special conditions whereby the investigator has a shorter approval period or must report research progress at specific intervals. Continuation of projects past the approval period requires submission of the Application for Continued Approval/Final Report form to the Board. It is the responsibility of the investigator to submit the application form and obtain approval for project continuation from the HREB prior to expiration of the approved period. It is also the responsibility of the investigator to submit the Application for Continued Approval/Final Report at the conclusion of the project. Investigators will be notified of the need for renewal 60 days prior and again 30 days prior to the end date of the HREB approval period. Projects for which the HREB will require verification from sources other than the investigator that no material changes have occurred are:
				1. Those involving high risk to human participants, or
				2. Those directed by investigators who have previously been found in non-compliance with institutional and Federal policy.
				3. Projects where concern about possible material changes occurring without HREB approval have been raised based upon information provided in continuing review reports or from other sources.
			9. Investigators will be notified in writing (and may be notified by telephone) of Board action or of the need for modifications required as a condition for HREB approval of the proposed research. The HREB will determine whether the modifications need to be submitted to the full HREB or whether they may be reviewed by the Chair or Chair’s designee. The applicant returns the modifications to the Office of Sponsored Programs. They are distributed to the full HREB or the Chair (or the Chair’s designee) as per the Board’s decision. These are examined and either an approval letter is initiated or a request for further modification is made. The Office of the Provost/Vice President for Academic Affairs will be notified of approvals, modification requirements and disapprovals in writing.
			10. When the research activity involves an outside agency (e.g., hospital, public school, clinic) the investigator must secure written approval from the appropriate official within the agency prior to receipt of final approval from the HREB. The status of the research project will be "Approval Withheld Pending External Site Approval" until the final approval from the external site is received by the HREB. (Investigators must first secure this project review status before applying for External Site Approval.)
			11. If the HREB gives the research proposal an Approval Withheld Pending status, the investigator must contact the Board Chair regarding the required actions within 60 days or the proposal will be withdrawn from further Board action.
			12. Research protocols scheduled for review shall be distributed to all members of the HREB at least two weeks prior to the meeting.
			13. When it is determined that consultants or experts will be required to advise the HREB in its review, the research protocol or appropriate sections shall also be distributed to the consultants or experts prior to the meeting if determined by Chair to be necessary. These individuals may not vote with the HREB.
			14. For both initial and continuing review, protocols that also involve grant applications to external agencies, the Chair or Chair’s designee will function as a primary reviewer and will review the entire grant application as well as the protocol.
			15. All HREB initial review and continuing review shall be conducted at convened meetings and at timely intervals. Exceptions to this requirement are studies which meet the requirements for expedited continuing review as stated in Appendix B of the Human Research Ethics Board Manual, F. (8) and F. (9).
			16. A majority of the membership of the HREB constitutes a quorum and is required in order to convene a meeting for the review of research protocols. Members on official leaves of absence (e.g., medical, sabbatical, summer, etc.) will not be considered as active members in the determination of quorum. Members in training will be considered for determination of quorum but are to abstain from voting on research protocols until training is completed.
			17. An HREB member whose concerns are primarily in non-scientific areas must be present at the convened meeting before the HREB can conduct its review of research.
			18. For a research protocol to be approved, it must receive the approval of a majority of those voting members present at the convened meeting.
			19. The HREB may not have a member participating in the HREB's initial or continuing review of any project in which the member has a conflict of interest, except to provide information requested by the HREB. (If quorum is at risk, the member with the conflict of interest, will leave the room for discussion and will return for a secret ballot vote in which that member submits a signed abstention.)
		3. Expedited Review Procedures
			1. The only categories of research for which the HREB may use an initial expedited review procedure are those which are specified in Part II, C.3.e., or Appendix B of the Human Research Ethics Board Manual.
				1. The research investigator submits their protocol application using the PACS system and uploads the completed Template Proposal for Research Review-Long Form, the informed consent document, and other materials as necessary. The application must provide full justification to support expedited review in relation to the appropriate category listed in Part II, C.3.e.
				2. Applications may be submitted at any time. However, if the investigator has any questions about the applicability of the expedited review status, they should submit the application at least three (3) weeks prior to scheduled HREB meetings to allow for full review if necessary.
			2. Expedited review shall be conducted by the HREB Chair or one or more of the experienced HREB members designated by the Chair to conduct the review. Reviews, checklists, and correspondence are to be submitted within 10 school days of receipt.
			3. The HREB members conducting the expedited review may exercise all of the authorities of the HREB except that the reviewer(s) may not disapprove the research. The reviewer(s) shall refer any research protocol which the reviewer(s) would have disapproved to the full committee for review. The reviewer(s) may also refer other research protocols to the full committee whenever the reviewer(s) believes that full committee review is warranted.
			4. When the expedited review procedure is used, the HREB Chair or member conducting the review shall inform the full HREB of research protocols which have been approved at the meeting following the review decision.
			5. An expedited procedure may also be used to review minor changes in approved research. Expedited review of minor changes may be conducted by the Chair or Chair’s designee for all changes except those which would increase risk to participants above a level of minimal risk.
			6. Approval of proposed research is usually granted for a period of 12 months commencing on the date approval is granted by the Board’s designee. The Board may request, when appropriate, that the investigator request continued approval of their study. The typical time frame would be 12 months commencing from the date approval is granted by the Board’s designee. If deemed necessary, a shorter approval period may be mandated. An annual administrative check-in will occur once a year. The HREB Coordinator will contact the Principal Investigator of all open Expedited and Full-board studies to assess the status of the study and to confirm whether the study is ongoing or closed.
		4. Exempt Review Procedures
			1. In the case of applications for certification of exempt status, review shall be conducted by the HREB Chair or by one or more of the experienced HREB members designated by the Chair.
			2. To determine whether to apply for exempt status, refer to Part II, A.1, or Appendix A of the Human Research Ethics Board Manual.
		5. Continuing Review Procedures
			1. For those studies specifically deemed to require continuing review, submission of the Application for Continued Approval/Final Report form to the Board is required. It is the responsibility of the investigator to submit the application form and to obtain approval for project continuation from the HREB prior to expiration of the approval period. It is also the responsibility of the investigator to submit the Application for Continued Approval/Final Report at the conclusion of the project. Investigators will be notified of the need for renewal 60 days prior, and again 30 days prior to the end date of the HREB approval period. Projects for which the HREB will require verification from sources other than the investigator that no material changes have occurred are:
				1. Those involving high risk to human participants, or
				2. Those directed by investigators who have previously been found in non-compliance with institutional and Federal policy.
				3. Projects where concerns about possible material changes occurring without HREB approval have been raised based upon information provided in continuing review reports or from other sources.
		6. Special Considerations
			1. [NP SOP 2019 International Research](https://www.newpaltz.edu/media/sponsored-programs/NP%20SOP%202019%20International%20Research%20-%20Accessible.docx)
			2. [NP SOP 2019 Prisoner Research Guidelines](https://www.newpaltz.edu/media/sponsored-programs/NP%20SOP%202019%20Prisoner%20Research%20Guidelines.docx)
			3. [NP SOP 2019 Making Qualtrics Surveys Anonymous](https://www.newpaltz.edu/media/sponsored-programs/NP%20SOP%202019%20Making%20Qualtrics%20Surveys%20Anonymous.docx)
			4. [NP SOP 2019 MTurk Guidelines](https://www.newpaltz.edu/media/sponsored-programs/NP%20SOP%202019%20MTurk%20Guidelines.pdf)
1. Documentation and Records
	1. HREB Records
		1. Within the PACS electronic management system, the institution (or, when appropriate, the HREB) shall prepare and maintain adequate documentation of HREB activities, including the following:
			1. Copies of all research proposals reviewed, relevant decisions scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to participants.
			2. Minutes of HREB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the HREB; the vote on these actions including number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; a written summary of the discussion of controverted issues and their resolution; and documentation of determinations the HREB is required to make.
			3. Records of continuing review activities.
			4. Copies of all correspondence between the HREB and the investigators.
			5. A list of HREB members in the same detail as described in 46.103(b) will be available on the HREB website and in the PACS library.
			6. Written procedures for the HREB in the same detail as described in 46.103(b) (4) and (5) will be available on the HREB website and in the PACS library.
			7. Statements of significant new findings provided to participants, as required by 46.116(b) (5).
			8. The records required by this policy shall be retained for at least three years, and records relating to research which was conducted shall be retained for at least three years after completion of the research. These records will be stored securely in the PACS electronic management system. All records shall be accessible for inspection and copying by authorized representatives of Federal departments or agencies that conduct, support or regulate the research at reasonable times and in a reasonable manner.
2. Standard Operating Policies
	1. [HREB Appeals Process - Approved June 24, 2020](https://www.newpaltz.edu/media/sponsored-programs/HREB%20Appeals%20Process%20-%20Approved%20June%2024%2C%202020.docx)
	2. [NP SOP 2019 Audio Video Digital Policy](https://www.newpaltz.edu/media/sponsored-programs/NP%20SOP%202019%20Audio%20Video%20Digital%20Policy.docx)
	3. [NP SOP 2019 Definitions](https://www.newpaltz.edu/media/sponsored-programs/NP%20SOP%202019%20Definitions%20-%20Accessible.docx)
	4. [NP SOP 2019 Exempt Categories](https://www.newpaltz.edu/media/sponsored-programs/NP%20SOP%202019%20Exempt%20Categories.docx)
	5. [NP SOP 2019 Exemption Categories](https://www.newpaltz.edu/media/sponsored-programs/NP%20SOP%202019%20Exemption%20Categories%20-%20Accessible.pdf)
	6. [NP SOP 2019 Expedited Categories](https://www.newpaltz.edu/media/sponsored-programs/NP%20SOP%202019%20Expedited%20Categories%20-%20Accessible.pdf)
	7. [NP SOP 2019 Research Subject To Human Subjects Regulations](https://www.newpaltz.edu/media/sponsored-programs/NP%20SOP%202019%20Research%20Subject%20To%20Human%20Subjects%20Regulations.pdf)
	8. [NP SOP 2023 Student Research Exercises and Not Human Subjects Research Policy](https://www.newpaltz.edu/media/sponsored-programs/NP%20SOP%202023%20Student%20Research%20Exercises%20and%20Not%20Human%20Subjects%20Research%20Policy.docx)
	9. [NP SOP 2019 Exempt Review by Instructor](https://www.newpaltz.edu/media/sponsored-programs/NP%20SOP%202019%20Exempt%20Review%20by%20Instructor%20-%20Accessible.pdf)
	10. [NP SOP 2019 External Site approval policy](https://www.newpaltz.edu/media/sponsored-programs/NP%20SOP%202019%20External%20Site%20approval%20policy.pdf)
	11. [NP SOP 2019 External Researcher Policy](https://www.newpaltz.edu/media/sponsored-programs/NP%20SOP%202019%20External%20Researcher%20Policy.pdf)
	12. [NP SOP 2023 Informed Consent for Exempt Studies Policy](https://www.newpaltz.edu/media/sponsored-programs/Informed%20Consent%20for%20Exempt%20Studies%20Policy.docx)
	13. [NP SOP 2019 International Research](https://www.newpaltz.edu/media/sponsored-programs/NP%20SOP%202019%20International%20Research%20-%20Accessible.docx)
	14. [NP SOP 2019 IRB Considerations for Privacy and Confidentiality Safeguards](https://www.newpaltz.edu/media/sponsored-programs/NP%20SOP%202019%20IRB%20Considerations%20for%20Privacy%20and%20Confidentiality%20Safeguards.docx)
	15. [NP SOP 2019 IRB Agreement Authorization](https://www.newpaltz.edu/media/sponsored-programs/NP%20SOP%202019%20IRB%20Agreement%20Authorization.docx)
	16. [NP SOP 2019 Prisoner Research Guidelines](https://www.newpaltz.edu/media/sponsored-programs/NP%20SOP%202019%20Prisoner%20Research%20Guidelines.docx)
	17. [NP SOP 2019 Engagement in Research](https://www.newpaltz.edu/media/sponsored-programs/NP%20SOP%202019%20Engagement%20in%20Research-1.pdf)
	18. [NP SOP 2019 Study Completion Reporting Policy](https://www.newpaltz.edu/media/sponsored-programs/NP%20SOP%202019%20Study%20Completion%20Reporting%20Policy%20-%20Accessible.docx)
	19. [NP SOP 2019 Email Lists Student Research](https://www.newpaltz.edu/media/sponsored-programs/NP%20SOP%202019%20Email%20Lists%20Student%20Research.pdf)
	20. [NP SOP 2019 Use of Surrogates Policy](https://www.newpaltz.edu/media/sponsored-programs/NP%20SOP%202019%20Use%20of%20Surrogates%20Policy%20Revised%20January%2031%2C%202023.docx)
	21. [NP SOP 2019 Making Qualtrics Surveys Anonymous](https://www.newpaltz.edu/media/sponsored-programs/NP%20SOP%202019%20Making%20Qualtrics%20Surveys%20Anonymous.docx)

* 1. [NP SOP 2019 MTurk Guidelines](https://www.newpaltz.edu/media/sponsored-programs/NP%20SOP%202019%20MTurk%20Guidelines.pdf)
	2. [NP SOP 2019 Adjunct Faculty Policy for Human Participants Research](https://www.newpaltz.edu/media/sponsored-programs/NP%20SOP%202019%20Adjunct%20Faculty%20Policy%20for%20Human%20Subjects%20Research.pdf)
	3. [NP SOP 2019 Student Policy For Human Participants Research](https://www.newpaltz.edu/media/sponsored-programs/NP%20SOP%202019%20Student%20Policy%20For%20Human%20Subjects%20Research.pdf)
	4. [NP SOP 2020 Noncompliance](https://www.newpaltz.edu/media/sponsored-programs/NP%20SOP%202020%20Noncompliance.pdf)
	5. [NP SOP Policy for Dealing with Protocol Information Requests 2021](https://www.newpaltz.edu/media/sponsored-programs/NP%20SOP%20Policy%20for%20Dealing%20with%20Protocol%20Information%20Requests%202021.docx)
1. Special Topics
	1. Mandatory Reporting
		1. Some researchers may find themselves in the dual role of researcher and mandatory reporter.
		2. In New York State, some researchers may find themselves in this dual role. As such, it’s important for [Mandatory Reporters](https://ocfs.ny.gov/publications/Pub1159/OCFS-Pub1159.pdf) to know their ethical and legal obligations.
		3. [New York State Sanitary Code (10NYCRR 2.10)](https://www.health.ny.gov/professionals/diseases/reporting/communicable/) requires reporting of suspected and/or confirmed communicable diseases by health professionals. Specific diseases requiring reporting can be found under [Communicable Disease Reporting Requirements.](https://www.health.ny.gov/forms/instructions/doh-389_instructions.pdf).
	2. Certificates of Confidentiality
		1. Certificates of Confidentiality are issued by the National Institutes of Health (NIH) and other HHS agencies to protect identifiable research information from forced or compelled disclosure.
		2. They allow the investigator and others who have access to research records to refuse to disclose identifying information on research participants in civil, criminal, administrative, legislative, or other proceedings, whether federal, state, or local.
		3. For more information, please look at the [Office of Human Research Protections](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/certificates-of-confidentiality/index.html) or the NIH for the most recent guidance.
	3. Department of Education
		1. Research involving educational settings may involve state and federal laws.
		2. For information on the federal requirements for conducting research in educational institutions, please read the guidance for the US Department of Education on their Website titled [Protection of Human Subjects in Research](https://www2.ed.gov/about/offices/list/ocfo/humansub.html).
		3. Researchers are responsible to ensure their research is conducted in accordance with these laws.
			1. [Family Educational Rights and Privacy Act](https://studentprivacy.ed.gov/node/548/) (FERPA)
			2. [Protection of Pupil Rights Amendment](https://studentprivacy.ed.gov/content/ppra) (PPRA)
	4. HIPAA
		1. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) contains numerous factors related to the Conduct of Research.
		2. The HIPAA Privacy Rule establishes the conditions under which protected health information may be used or disclosed by covered entities for research purposes.
		3. For more guidance, please look at the following documents:
			1. Health and Human Services [Guidance on HIPAA and Research](https://www.hhs.gov/hipaa/for-professionals/special-topics/research/index.html)
			2. NIH’s FAQ titled [HIPAA Privacy Rule for Researchers](https://privacyruleandresearch.nih.gov/faq.asp)
2. UPDATING POLICIES
	1. This procedure establishes the process to create and update standard operating procedures (SOPs) and associated checklists and worksheets.
	2. The process begins when the HREB Coordinator, HREB Chair/Associate Chair, HPA, or Signatory Official acknowledges that a standard operating procedure needs to be created or modified.
	3. All new SOPs will be evaluated and voted on by the HREB during a convened meeting.
		1. For a new standard operating procedure, assign a number.
		2. Assign an author and approver.
		3. Have the author create or update the standard operating procedure following the “TEMPLATE SOP” or update the associated checklist or worksheet.
		4. Have the approver review and approve the document.
		5. Once approved by the approver:
		6. Update the approval date.
			1. File the approved new or revised document in the standard operating procedure files.
			2. Post the approved procedure on the Human Research Ethics Board website.
			3. File the old document, if any, in the standard operating procedure files.
			4. Send an email to affected individuals informing them of the change.
	4. The process ends when the new or revised standard operating procedure has been approved and filed.
3. REVISIONS FROM PREVIOUS VERSION
	1. This document represents the first update of the Policy on the Use of Human Participants in Research since 2006.
4. Policy
	1. None
5. Responsibilities
	1. This document spells out the responsibilities of all entities involved with human participants research at SUNY New Paltz.
	2. Researchers must conduct their research in accordance with the relevant policies in this document and those provided in other HREB SOPs.
6. Procedure For Updating This Document
	1. This document is not designed to be a stagnant document.
	2. With the evolving nature of human research participant ethics, this document should be evaluated annually to ensure that the information is up to date with all Federal and State requirements for human participants research.
7. References
	1. SUNY Down State Medical Center’s [Human Research Protections Program](https://www.downstate.edu/research/_documents/irb/policies/policy_irb-01%2002.03.2021.pdf)
	2. SUNY Stonybrook’s [Human Subjects: Standard Operating Procedures](https://www.stonybrook.edu/commcms/research-compliance/_pdf/Policies%20that%20include%20information%20from%20the%20Final%20Rule.pdf)
	3. DHHS: [Code of Federal Regulations, Title 45 Part 46: Protection of Human Subjects](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML)
	4. [The Belmont Report](https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html): "[Ethical Principles and Guidelines for the Protection of Human Subject of Research](https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html)"