

The New England School of Acupuncture (NESA), in compliance with the terms of the Federalwide Assurance of Protection for Human Subjects, agrees to the following terms:

1. Human Subject Research Will be Guided by Ethical Principles

All of NESA's human subject activities and all activities of its Institutional Review Board (IRB) designated under the Assurance, regardless of funding source, will be guided by the ethical principles in: (a) The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects, or (b) other appropriate ethical standards recognized by Federal Departments and Agencies that have adopted the Federal Policy for the Protection of Human Subjects.

These terms apply whenever the NESA becomes engaged in federally-supported* (i.e., conducted or supported) human subject research, which is not otherwise exempt from the Federal Policy for the Protection of Human Subjects. The NESA becomes so engaged whenever (a) its employees or agents intervene or interact with human subjects for purposes of federally-supported research; (b) its employees or agents obtain individually identifiable private information about human subjects for purposes of federally-supported research; or (c) NESA receives a direct federal award to conduct human subject research, even where all activities involving human subjects are carried out by a subcontractor or collaborator.

*[*Federally-supported is defined throughout the FWA and the Terms of Assurance as the U.S. Government providing any funding or other support (including, but not limited to, providing supplies, products, drugs, and identifiable private information collected for research purposes) and/or the conduct of the research involves U.S. Government employees.]*

2. Compliance with the Federal Policy for the Protection of Human Subjects

In the process of conducting federally-supported human subject research NESA and its IRB, which has been designated under NESA's Assurance will comply with the Federal Policy for the Protection of Human Subjects, known as the Common Rule. All federally-supported human subject research will also comply with any additional human subject regulations and policies of the supporting Department or Agency. All human subject research conducted or supported by the Department of Health and Human Services (DHHS) will comply with all Subparts of DHHS regulations at Title 45 Code of Federal Regulations Part 46 (45 CFR 46 and its Subparts A, B, C, and D).

3. Written Procedures

a) NESA has established, and will provide a copy to OHRP upon request, written procedures for:

- 1) ensuring prompt reporting to the IRB, appropriate institutional officials, the relevant Department or Agency Head, any applicable regulatory body, and OHRP of any: (i) unanticipated problems involving risks to subjects or others, (ii) serious or continuing noncompliance with the Federal Regulations or IRB requirements, and (iii) suspension or termination of IRB approval.

- 2) NESA will verify by the IRB Chair, in consultation with IRB members and other than the investigator or research team, whether proposed human subject research activities qualify for exemption from the requirements of the Common Rule;

b) The NESA IRB(s) has established, and will provide a copy to OHRP upon request, written procedures for:

1) Conducting IRB initial and continuing review (not less than once per year), approving research, and reporting IRB findings to the investigator and the Institution;

2) Determining which projects require review more often than annually and which projects need verification from sources other than the investigator that no material changes have occurred since the previous IRB review;

3) Ensuring that changes in approved research protocols are reported promptly and are not initiated without IRB review and approval, except when necessary to eliminate apparent immediate hazards to the subject.

4. Responsibilities and Scope of the NESAs IRB

Except for research exempted or waived in accordance with Sections 101(b) or 101(i) of the Common Rule, all human subject research will be reviewed, prospectively approved, and subject to continuing oversight and review at least annually by the NESAs IRB. The IRB will have authority to approve, require modifications in, or disapprove the covered human subject research.

5. Informed Consent Requirements

Except for research exempted or waived in accordance with Sections 101(b) or 101(i) of the Common Rule, informed consent will be:

a) sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by Section 116 of the Common Rule;

b) appropriately documented, in accordance with, and to the extent required by Section 117 of the Common Rule.

6. Requirement for Assurances for Collaborating Institutions/Investigators

NESA is responsible for ensuring that all institutions and investigators engaged in its U.S. federally-supported human subject research operate under an appropriate OHRP or other federally-approved Assurance for the protection of human subjects. In some cases, one institution may operate under an Assurance issued to another institution with the approval of the supporting Department or Agency and the institution holding the Assurance.

7. Written Agreements with Non-Affiliated Investigators

The engagement in human research activities of each independent investigator who is not an employee or agent of the Institution may be covered under the FWA only in accordance with a formal, written agreement of commitment to relevant human subject protection policies and IRB oversight. NESAs will maintain commitment agreements on file and provide copies to OHRP upon request

8. Institutional Support for the IRB(s)

NESA will provide the IRB that it operates with resources and professional and support staff sufficient to effectively carry out their responsibilities under the Assurance.

9. Compliance with the Terms of Assurance

NESA accepts and will follow items 1-8 above and is responsible for ensuring that (a) the IRB(s) designated under the Assurance agree to comply with these terms; and (b) the IRB(s) possesses appropriate knowledge of the local research context for all research covered under the Assurance (please refer to the OHRP guidance on IRB Knowledge of Local Research Context on the OHRP website).

Any designation under this Assurance of another Institution's IRB or an independent IRB must be documented by a written agreement between NESA and the IRB organization outlining their relationship and include a commitment that the designated IRB will adhere to the requirements of this Assurance. This agreement should be kept on file at both organizations and made available to OHRP upon request.

10. Assurance Training

The OHRP Assurance Training Modules describe the major responsibilities of the Institutional Signatory Official, the Human Protection Administrator, and the IRB Chair that must be fulfilled under the Assurance. NESA agrees to require these modules for the individuals mentioned, and to comply with the responsibilities outlined in these modules

11. Educational Training

NESA and its IRB have established educational training and oversight mechanisms (appropriate to the nature and volume of its research) to ensure that research investigators, IRB members and staff, and other appropriate personnel maintain continuing knowledge of, and comply with, relevant ethical principles, relevant Federal Regulations, OHRP guidance, other applicable guidance, state and local laws, and institutional policies for the protection of human subjects. Furthermore, NESA has established a policy requiring that a) IRB members and staff complete relevant educational training before reviewing human subject research; and b) research investigators complete appropriate institutional educational training before conducting human subject research.

12. Renewal of Assurance

NESA will update this Assurance at least every 36 months (3 years), even if no changes have occurred, in order to maintain an active Assurance. NESA is aware that failure to update this information may result in restriction, suspension, or termination of the Institution's FWA for the protection of human subjects.

IRB ORGANIZATION INFORMATION

IORG0001918 - New England Sch Acupuncture

Located at: Watertown, MASSACHUSETTS

Expires: March 29, 2008