

FEDERALWIDE ASSURANCE OF COMPLIANCE WITH DHHS REGULATIONS

FOR PROTECTION OF HUMAN RESEARCH SUBJECTS

9-5-07 to 9-5-11

State University of New York, State College of Optometry, hereinafter known as the "institution" (see Appendix A), hereby gives assurance, as specified below, that it will comply with the Department of Health and Human Services (DHHS) regulations for the protection of human research subjects, 45 CFR Part 46, as amended to include provisions of the Federal Policy for the Protection of Human Subjects (56FR28003) as Subpart A, and as may be further amended during the approval period for this Assurance.

PART 1 - PRINCIPLES, POLICIES, AND APPLICABILITY

I. Ethical Principles

- A. This institution is guided by the ethical principles regarding all research involving humans as subjects, 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"]), regardless of whether the research is subject to Federal regulation or with whom conducted or source of support (i.e., sponsorship).
- B. All institutional and non-institutional performance sites for this institution, domestic or foreign, will be obligated by this institution to conform to ethical principles which are at least equivalent to those of this institution, as cited in the previous paragraph or as may be determined by the DHHS Secretary.

II. Institutional Policy

- A. All requirements of Title 45, Part 46, of the Code of Federal Regulations (45 CFR 46) will be met for all **federally-sponsored** research, and all other human subject research regardless of sponsorship, except as otherwise noted in this Assurance. Federal (all departments and agencies bound by the Federal Policy) funds for which this Assurance applies may not be expended for research involving human subjects unless the requirements of this Assurance have been satisfied.

B. Except for those categories specifically exempted or waived under Section 101(b)(1-6) or 101(i), all research covered by this Assurance will be reviewed and approved by an Institutional Review Board (IRB) which has been established under a Multiple Project Assurance (MPA) with OPRR **or as may be otherwise agreed to by OPRR** (see Part 1, II, G). The involvement of human subjects in research covered by this Assurance will not be permitted until an appropriate IRB has reviewed and approved the research protocol and informed consent has been obtained from the subject or the subject's legal representative (see Sections 111, 116, and 117), **unless properly waived by the IRB under Section 116 ©, (d) or by any applicable waiver under Section 101 (i).**

C. This institution assures that before human subjects are involved in nonexempt research covered by this Assurance, the IRB will give proper consideration to:

1. the risks to the subjects,
2. the anticipated benefits to the subjects and others,
3. the importance of the knowledge that may reasonably be expected to result, and
4. the informed consent process to be employed.

D. Certification of IRB review and approval for all Federally-sponsored research involving human subjects will be submitted to the **Office of the Associate Dean for Graduate Studies and Research**, hereinafter known as the Office of Research Administration (ORA), for forwarding to the appropriate Federal department or agency. Compliance will

occur within the time and in the manner prescribed for forwarding certifications of IRB review to DHHS or other Federal departments or agencies for which this Assurance applies.

As provided for under section 118, applications and proposals lacking definite plans for involvement of human subjects will not require IRB review and approval prior to award. However, except for research exempted or waived under Section 101 (b) or (i), no human subjects may be involved in any project supported by such awards until IRB review and approval has been certified to the appropriate Federal department or agency.

As required under Section 119, the IRB will review **proposed** and recommend approval for involvement of human subjects in Federal research activities **undertaken without** prior intent for such involvement, but will not permit such involvement until certification of the IRB's review and approval is received by the appropriate Federal department or agency.

E. Institutions that are not direct signatories to this Assurance are not authorized to cite this Assurance. This institution will ensure that such other institutions and investigators not bound by the provisions of this Assurance for DHHS-sponsored research will satisfactorily assure compliance with 45 CFR 46, as required (see Part 2, I, D and II, K), as a prior condition for involvement in **DHHS-sponsored** human subject research which

is under the auspices of this institution (see Part 1, III, A). Institutions that have entered into an Inter-Institutional Amendment (IIA) to this Assurance must submit a Single Project Assurance (SPA) to the Office for Protection from Research Risks (OPRR) of DHHS for DHHS-sponsored research, on request, when that research is not conducted under the auspices of a signatory institution to this Assurance.

- F. This institution will ensure that any **collaborating entities (i.e., those entities engaged in human subject research by virtue of subject accrual, transfer of identifiable information, and/or in exchange of something of value, such as material support [e.g., money, drugs, or identifiable specimens], co-authorship, intellectual property, or credits)** materially engaged in the conduct of non-federally sponsored research involving human subjects will possess mechanisms to protect human research subjects that are at least equivalent to those procedures provided for in the ethical principles to which this institution is committed (see Part 1, I).
- G. This institution will comply with the requirements set forth in Section 114 of the regulations regarding cooperative research projects. When research covered by this Assurance is conducted at or in cooperation with another entity, all provisions of this Assurance remain in effect for that research. This institution may accept, for the purpose of meeting the IRB review requirements, the review of an IRB established under another DHHS MPA. Such acceptance must be (a) in writing, (b) approved and signed by an official of this institution's Office of Research Administration(s), and (c) approved and signed by correlative officials of each of the other cooperating institutions. A copy of the signed understanding will serve as an addendum to this Assurance and will be forwarded to the OPRR of DHHS by the ORA(s) **for OPRR approval.**
- H. This institution will exercise appropriate administrative overview to ensure that the institution's policies and procedures designed for protecting the rights and welfare of human subjects are being effectively applied in compliance with this Assurance.
- I. **Description of this institution's policy for the protection of human subjects is contained in its internal written procedures which are available to OPRR and other Federal departments or agencies, upon request. Appendix D to this assurance abstracts pertinent organizational, personnel, and reporting procedures sufficient to describe the substance and relative prominence conferred upon the protection of subjects.**

III. Applicability

- A. Except for research in which the only involvement of humans is in one or more of the categories exempted or waived under Section 101(b)(1-6) or 101(i), this Assurance applies to all research involving human subjects, and all other activities which even in part involve such research, regardless of sponsorship, if one or more of the following apply:
 - 1. the research is sponsored by this institution, or

2. the research is conducted by or under the direction of any employee or agent of this institution in connection with his or her institutional responsibilities, or
 3. the research is conducted by or under the direction of any employee or agent of this institution using any property or facility of this institution, or
 4. the research involves the use of this institution's non-public information to identify or contact human research subjects or prospective subjects.
- B. All human subject research which is exempt under Section 101(b)(1-6) or 101(i) will be conducted in accordance with: (1) the Belmont Report, (2) this institution's administrative procedures to ensure valid claims of exemption, and (3) orderly accounting for such activities.
- C. Components of this institution are bound by the provisions of this Assurance. Those components which can be expected to participate in human subject research sponsored by DHHS or other Federal departments or agencies for which this Assurance will apply are identified in Appendix A. Appendix A will be revised as changes occur and revisions forwarded to OPRR.
- D. This Assurance must be accepted by other Federal departments or agencies that are bound by the Federal Policy for the Protection of Human Subjects when appropriate for the research in question and therefore applies to all human subject research so sponsored.⁽¹⁾ Research that is neither conducted nor supported by a Federal department or agency but is subject to regulation as defined in Section 102(e) must be reviewed and approved, in compliance with Sections 101, 102, and 107 through 117.

PART 2 - RESPONSIBILITIES

I. Institution

- A. This institution acknowledges that it bears full responsibility for the performance of all research involving human subjects, covered by this Assurance, including complying with Federal, state, or local laws as they may relate to such research.
- B. This institution will require appropriate additional safeguards in research that involves: (1) fetuses, pregnant women, or human ova in vitro fertilization (see 45 CFR 46 Subpart B), (2) prisoners (see 45 CFR 46 Subpart C), (3) children (see 45 CFR 46 Subpart D), (4) the cognitively impaired, or (5) other potentially vulnerable groups.
- C. This institution, including all its named components (see Appendix A), acknowledges and accepts its responsibilities for protecting the rights and welfare of human subjects of research covered by this Assurance.

- D. This institution is responsible for acquiring appropriate Assurances or Amendments, when requested, and certifications of IRB review and approval for federally sponsored research from all its standing affiliates (see Appendix B) and Assurances or Agreements for all others, domestic or foreign, which may otherwise become affiliated on a limited basis in such research.
- E. This institution is responsible for ensuring that **no performance site** cooperating in the conduct of federally sponsored research for which this Assurance applies do so without **Federal department or agency approval of** an appropriate assurance of compliance, **in whatever appropriate form**, and satisfaction of IRB certification requirements.
- F. In accordance with the compositional requirements of Section 107, this institution has established an IRB listed in the attached roster (see Appendix C). Certain research supported by the U.S. Department of Education will be reviewed in accordance with the requirements of Title 34 CFR Parts 350 and 356 which require that the IRB include one person who is primarily concerned with the welfare of handicapped children or mentally **disabled** persons.
- G. This institution will provide both meeting space and sufficient staff to support the IRB's review and record-keeping duties.
- H. This institution recognizes that involvement in research activities of any OPRR-recognized Cooperative Protocol Research Programs (**CPRPs**) will involve additional reporting and record-keeping requirements related to human subject protections.
- I. This institution is responsible for ensuring that it and all its affiliates comply fully with all applicable Federal policies and guidelines, including those concerning notification of seropositivity, counseling, and safeguarding confidentiality where research activities directly or indirectly involve the study of human immunodeficiency virus (HIV).

II. Office of Research Administration for Human Subject Research (ORA)

- A. The ORA will receive from investigators, through their supervisors, all research protocols which involve human subjects, keep investigators informed of decisions and administrative processing, and return all disapproved protocols to them.
- B. The ORA is responsible for reviewing the preliminary determinations of exemption by investigators and supervisors and for making the final determination based on Section 101 of the regulations. Notice of concurrence for all exempt research will be promptly conveyed in writing to the investigator. All nonexempt research will be forwarded to the appropriate IRB.
- C. The ORA will make the preliminary determination of eligibility for expedited review procedures (see Section 110). Expedited review of research activities will not be permitted where full board review is required.

- D. The ORA will review all research (whether exempt or not) and decide whether the institution will permit the research. If approved by the IRB, but not permitted by the ORA, the ORA will promptly convey notice to the investigator and the IRB Chair. Neither the ORA nor any other office of the institution may approve a research activity that has been disapproved by the appropriate IRB.
- E. The ORA will forward certification of IRB approval of proposed research to the appropriate Federal department or agency only after all IRB-required modifications have been incorporated to the satisfaction of the IRB.
- F. The ORA will designate procedures for the retention of signed consent documents for at least three years past completion of the research activity.
- G. The ORA will maintain and arrange access for inspection of IRB records as provided for in Section 115.
- H. The ORA is responsible for ensuring constructive communication among the research administrators, department heads, research investigators, clinical care staff, human subjects, and institutional officials as a means of maintaining a high level of awareness regarding the safeguarding of the rights and welfare of the subjects.
- I. The ORA will arrange for and document in its records that each individual who conducts or reviews human subject research has first been provided with a copy of this Assurance, as well as with ready access to copies of 45 CFR 46, regulations of other Federal departments or agencies as may apply, the Belmont Report, and all other pertinent Federal policies and guidelines related to the involvement of human subjects in research.
- J. The ORA will report promptly to the IRB, appropriate institutional officials, the Office for Protection from Research Risks (OPRR), and any other sponsoring Federal department or agency head:
 - 1. any injuries to human subjects or other unanticipated problems involving risks to subjects or others,
 - 2. any serious or continuing noncompliance with the regulations or requirements of the IRB, and
 - 3. any suspension or termination of IRB approval for research.
- K. The ORA will ensure (a) solicitation (**or confirmation where applicable assurances to comply already exist**), receipt, and management of all assurances of compliance (whatever the appropriate format), and (b) certifications of IRB review (where appropriate) for **all performance sites** to this institution (including those listed in Appendix B), and subsequent submission of **new** documents to the proper **Federal department or agency** authorities (e.g., **OPRR for DHHS**) as a condition for

involvement in human subject research activities sponsored by DHHS or any other Federal department or agency for which this Assurance applies.

- L. The ORA will ensure that all affiliated performance sites that are not otherwise required to submit assurances of compliance with Federal regulations for the protection of research subjects at least document mechanisms to implement the equivalent of ethical principles to which this institution is committed (see Part 1, I).
- M. When an IRB of this institution accepts responsibility for review of research which is subject to this Assurance and conducted by any independent investigator who is not otherwise subject to the provisions of this Assurance, the ORA will obtain and retain an Non-institutional Investigator Agreement (NIA) **for CPRP activities (with copy to the investigator and the authorizing CPRP) or (b) obtain an Agreement for an Independent Investigator (AII) for review and approval by the appropriate Federal department or agency for non-CPRP activities** to document the investigator's commitment to abide: (1) by the same requirements for the protection of human research subjects as does this institution(s) and (2) the determinations of the IRB.
- N. The ORA assumes responsibility for ensuring conformance with special reporting requirements for any OPRR-recognized **CPRPs** in which the signatory institution(s) participate(s).
- O. The ORA will be responsible for procedural and record-keeping audits not less than once every year for the purpose of detecting, correcting, and reporting (as required) administrative and/or material breaches in uniformly protecting the rights and welfare of human subjects as required at least by the regulations and as may otherwise be additionally required by this institution(s).
- P. The ORA will ensure compliance with the requirements set forth in this Assurance and Section 114 regarding cooperative research projects. In particular, where the IRB of another institution with a DHHS MPA is relied upon, the ORA will ensure documentation of this reliance will be (a) in writing, (b) approved and signed by the ORA, (c) approved and signed by the correlative officials of each of the other cooperating institutions, and (d) retained by the ORA for at least three years past completion **of the research project, if limited in scope to a specific research project or retained as a permanent addendum to the MPA if not restricted to a specific project. For all Cooperative Agreements (CAs), the ORA will forward a copy of the required signed understanding to OPRR for **approval and** inclusion in this Assurance as an addendum.**

III. Institutional Review Board (IRB)

- A. The IRB will review, and have the authority to approve, require modification in, or disapprove all research activities, including proposed changes in previously approved human subject research. For approved research, the IRB will determine which activities

require continuing review more frequently than every twelve months or need verification that no changes have occurred if there was a previous IRB review and approval.

- B. IRB decisions and requirements for modifications will be promptly conveyed to investigators and the ORA, in writing. Written notification of decisions to disapprove will be accompanied by reasons for the decision with provision of an opportunity for reply by the investigator, in person or in writing.
- C. Initial and continuing convened IRB reviews and approvals will occur in compliance with 45 CFR 46 and provisions of this Assurance for each project unless properly found to be exempt (Section 101[b] and [i]) by the Office of Research Administration. Continuing reviews will be preceded by IRB receipt of appropriate progress reports from the investigator, including available study-wide findings.
- D. The IRB will observe the quorum requirements of Section 108(b). This institution's IRB has effective knowledge of subject populations, institutional constraints, differing legal requirements, and other factors which can foreseeably contribute to a determination of risks and benefits to subjects and subjects' informed consent and can properly judge the adequacy of information to be presented to subjects in accordance with requirements of Sections 103(d), 107(a), 111, and 116.
- E. The IRB will determine, in accordance with the criteria found at 45 CFR 46.111 and Federal policies and guidelines for involvement of human subjects in HIV research, that protections for human research subjects are adequate.
- F. The IRB will ensure that legally effective informed consent will be obtained and documented in a manner that meets the requirements of Sections 116 and 117. The IRB will have the authority to observe or have a third party observe the consent process.
- G. Where appropriate, the IRB will determine that adequate additional protections are ensured for fetuses, pregnant women, prisoners, and children, as required by Subparts B, C, and D of 45 CFR 46. The IRB will notify OPRR promptly when IRB membership(s) is modified to satisfy requirements of 45 CFR 46.304 and when the IRB fulfills its duties under 45 CFR 46.305(c).
- H. Scheduled meetings of the IRB for review of each research activity will occur not less than every 12 months and may be more frequent, if required by the IRB on the basis of degree of risk to subjects. The IRB may be called into an interim review session by the Chairperson at the request of any IRB member or institutional official to consider any matter concerned with the rights and welfare of any subject.
- I. The IRB will prepare and maintain adequate documentation of its activities in accordance with Section 46.115 and in conformance with Office of Research Administration requirements.

- J. The IRB will forward to the Office of Research Administration any significant or material finding or action, at least to include the following:
1. injuries or any other unanticipated problems involving risks to subjects or others,
 2. any serious or continuing noncompliance with the regulations or requirements of the IRB, and
 3. any suspension or termination of IRB approval.
- K. In accordance with Section 113, the IRB will have the authority to suspend or terminate previously approved research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects.
- L. The IRB for this institution will ensure effective input (consultants or voting or nonvoting members) for all initial and continuing reviews conducted on behalf of performance sites where there will be human research subjects. IRB minutes will document attendance of those other than regular voting members. The IRB list(s) in Appendix C includes those who are identified as knowledgeable about any affiliate institution having entered into an Inter-Institutional Amendment or other **institutional performance site for which an Assurance is required** when relying on one or more of the IRBs of this institution.
- M. The IRB will act with reasonable dispatch, upon request, to provide full board review of protocols of OPRR-recognized Cooperative Protocol Research Programs (CPRP). The IRB will not employ expedited review procedures for CPRP protocols when they are to be entered into for the purpose of research. Although emergency medical care based on such protocols is permitted without prior IRB approval, patients receiving emergency care under these conditions will not be counted as research subjects and resultant data will not be used for research purposes.
- N. Certifications of IRB review and approval will be forwarded through the ORA to the appropriate Federal department or agency for research sponsored by such departments or agencies.

IV. Research Investigator

- A. Research investigators acknowledge and accept their responsibility for protecting the rights and welfare of human research subjects and for complying with all applicable provisions of this Assurance.
- B. Research investigators who intend to involve human research subjects will not make the final determination of exemption from applicable Federal regulations or provisions of this Assurance.
- C. Research investigators are responsible for providing a copy of the IRB-approved and signed informed consent document to each subject at the time of consent, unless the IRB has specifically waived this requirement. All signed consent documents are to be retained in a manner approved by the Office of Research Administration.
- D. Research investigators will promptly report proposed changes in previously approved human subject research activities to the IRB. The proposed changes will not be initiated without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subjects.
- E. Research investigators are responsible for reporting progress of approved research to the Office of Research Administration, as often as and in the manner prescribed by the approving IRB on the basis of risks to subjects, but no less than once per year.
- F. Research investigators will promptly report to the IRB any injuries or other unanticipated problems involving risks to subjects and others.
- G. No research investigator who is obligated by the provisions of this Assurance, any associated Inter-Institutional Amendment, or Noninstitutional Investigator Agreement will seek to obtain research credit for, or use data from, patient interventions that constitute the provision of emergency medical care without prior IRB approval. A physician may provide emergency medical care to a patient without prior IRB review and approval, to the extent permitted by law (see Section 116[f]). However, such activities will not be counted as research nor the data used in support of research.
- H. Research investigators will advise the IRB, Office of Research Administration and the appropriate officials of other institutions of the intent to admit human subjects who are involved in research protocols for which this Assurance or any related Inter-Institutional Amendment or Non-institutional Investigator Agreement applies. When such admission is planned or a frequent occurrence, those institutions must possess an applicable OPRR-approved Assurance prior to involvement of such persons as human subjects in those research protocols.

V. Affiliated Institutions and Investigators (i.e., all performance sites, with or without IIAs)

- A. Each **performance site** to this institution that is involved in **federally** sponsored research activities must provide to the Office of Research Administration an appropriate written assurance of compliance with the Belmont Report and **the Federal Policy, to include Subparts B, C, and D or 45 CFR 46 where appropriate** (or equivalent protections if a foreign site), **for review and approval, as specified by the sponsoring Federal department or agency (e.g., by OPRR for DHHS), prior to involvement of human subjects or expenditure of funds or other support to do so.**
- B. Each **institutional performance site** must respond to a request by the Office of Research Administration of this institution for an Inter-Institutional Amendment, **SPA, or CPA** as appropriate, whichever is most suited to the circumstances.
- C. Each non-institutional **performance site** (e.g., a private practice physician not otherwise an employee of this institution or who otherwise would not ordinarily be bound by the provisions of this Assurance **or any other applicable institutional Assurance**) who is involved in human subject research of this institution must respond to a request by the Office of Research Administration of this institution for **either for an Agreement for an Independent Investigator or a Non-institutional Investigator Agreement, as appropriate, depending on the nature of the research activity.**
- D. Performance sites that are not legally inseparable components of this institution (whether an institutional or non-institutional **performance site**) are not authorized to cite this Assurance.

PART 3 - SIGNATURES

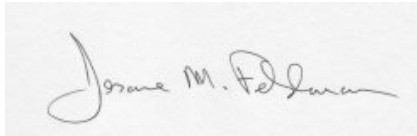
I. Institutional Endorsement(s)

The officials signing below assure that any research activity conducted, supported, or otherwise subject to DHHS or other Federal departments or agencies that are authorized to rely on this Assurance (Parts 1, 2, 3 and Appendices) or any other sources provided for in this Assurance, will be reviewed and approved by the appropriate IRB in accordance with the requirements of all applicable Subparts of Part 46, Title 45 of the Code of Federal Regulations, with this Assurance, and the stipulations of the IRB.

A. Primary Signatory Institution

1. AUTHORIZED INSTITUTIONAL OFFICIAL

Signature:



Date: 7/7/2007

Name: **Jerome Feldman**
Title: **Associate Dean for Graduate Programs and Research**
Institution and
Address: **State University of New York
State College of Optometry
33 W. 42th Street
New York NY 10036**

Phone: **212.938.5540**
Fax: **212.938-5537**
E-Mail: **jfeldman@sunyopt.edu**

2. PRIMARY CONTACT "SAME"

FOR DHHS USE ONLY

II. Office for Protection from Research Risks (DHHS) Approval

A. DHHS RECOMMENDING OFFICIAL

Signature: _____ Date: _____
 Name: Katherine Duncan, M.D.
 Title: Adjunct Medical Officer
 Address: Division of Human Subject Protections
Office for Protection from Research Risks (OPRR)
6100 Executive Boulevard, Room 3B01
(MSC 7507)
Rockville, Maryland 20892-7507

Phone: 301- 496-7005 X207
 Fax: 301- 402-0527
 E-Mail: kd41f@nih.gov

EFFECTIVE DATE OF ASSURANCE: _____

EXPIRATION DATE OF ASSURANCE: _____

B. DHHS APPROVING OFFICIAL

Signature: _____ Date: _____
 Name: _____
 Title: Assurance Coordinator, Assurance Branch
 Address: Division of Human Subject Protections
Office for Protection from Research Risks (OPRR)
6100 Executive Boulevard, Room 3B01
(MSC 7507)
Rockville, Maryland 20892-7507

Phone: 301- 496-7041 X
 Fax: 301- 402-0527
 E-Mail _____

DHHSMPA# M1242

Date: 7/7/07 _____

Appendix A

**COMPONENTS WHICH ARE LEGALLY INSEPARABLE FROM EACH
DESIGNATED SIGNATORY INSTITUTION AND ARE AUTHORIZED TO CITE THIS
MPA OR PARTICIPATE IN RESEARCH OF THE SIGNATORY**

MPA Signatory Institution #1 (i.e., Primary): State University of New York, State College of
Optometry

Components that Participate in Human Research:

Name:	City:	State
Signatory Institution Only	New York	New York

Appendix B

**STANDING AFFILIATES WHICH ARE LEGALLY SEPARATE FROM EACH
DESIGNATED SIGNATORY INSTITUTION WHERE OPRR-APPROVED INTER-
INSTITUTIONAL AMENDMENTS ARE REQUIRED**

MPA Signatory Institution #1 (Primary): College of Optometry, State University of New
York

Affiliate Institutions: None