PRINCIPLES, POLICIES, AND APPLICABILITY

1) Ethical Principles

A) This institution 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 Participants of Biomedical and Behavioral Research (entitled: Ethical Principles and Guidelines for the Protection of Human Participants of Research [the "Belmont Report"]), regardless of whether the research is subject to Federal regulations 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.

2) Institutional Policy

A) All requirements of Title 45, Part 46, and 21 CFR 56, of the Code of Federal Regulations (45 CFR 46) and Title 2, Part 52 (21 CFR 56), will be met for all applicable DHHS-supported research, and all other human participant research regardless of sponsorship. Federal (all departments and agencies bound by the Federal Policy) funds for which this Policy applies may not be expended for research involving human participants unless the requirements of this Policy have been satisfied.

B) Except for those categories specifically exempted or waived under 45 CFR 46.101, b, 1-6 or 101, i, all research covered by this Policy will be reviewed and approved by the Howard University Institutional Review Board (IRB) which has been established under a Federal Wide Assurance (FWA) issued to Howard University by the Office of Human Research Protection (OHRP). The involvement of human participants

in research covered by this Policy will not be permitted until the IRB has reviewed and approved the research protocol and informed consent has been obtained from the participant or the participant's legal representative according to 45 CFR 46.111, 116, and 117; and 21 CFR 50.27 and CFR 56.109.

C) At this institution, before human participants are involved in nonexempt research covered by this Policy, the IRB will give proper consideration to:

1. the risks to the participants,

2. the anticipated benefits to the participants 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 participants will be forwarded by the Chairman of the IRB, hereinafter referred to as the “Chairman”, on behalf of the Office of the Vice President for Research and Compliance, 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 these policies apply. As required under 45 CFR 46.119 and 21 CFR 56.109, the IRB will review and recommend approval for involvement of human participants in Federal research activities for which there was no 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 Policy are not authorized to cite this Policy. This institution will ensure

that such other institutions and investigators not bound by the provisions of this Policy for DHHS-sponsored research will satisfactorily assure compliance with 45 CFR 46 and 21 CFR 56, as required in their respective Parts: e.g., Part 2, I, D and II, K, as a prior condition for involvement in human participant research which is under the auspices of this institution according to all pertinent Parts of Federal Regulation, Part 1, III, A, Institutions that have entered into an Inter-Institutional Amendment (IIA) to this Policy must submit a statement of compliance with all relevant federal regulations conducted under the auspices of a signatory institution to this Policy.

F) This institution will ensure that any of its affiliates materially engaged in the conduct of non-federally sponsored research involving human participants will possess mechanisms to protect human research participants that are at least equivalent to those procedures provided for in the ethical principles to which this institution is committed according to Part 1, I.

G) This institution complies with the requirements set forth in 45 CFR 46.114 of the regulations regarding cooperative research projects. When research covered by this Policy is conducted at or in cooperation with another entity, all provisions of this Policy 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 Federal Wide Assurance. Such acceptance must be (a) in writing, (b) approved and signed by the Vice President for Research and Compliance, (c) approved and signed by correlative officials of each of the other cooperating institutions. The original of the signed understanding will serve as an addendum to this institution's FWA and will be forwarded to the OHRP of DHHS by the Vice President for Research and Compliance for 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 participants are being effectively applied in compliance with its FWA.

3) Applicability

A) Except for research in which the only involvement of humans is in one or more of the categories exempted or waived under 45 CFR 46.101 b, 1-6, or 101, I, and 21 CFR 56.105. This Policy applies to all research involving human participants, 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 participants or prospective participants.

B) All human participant research which is exempt under 45 CFR 46.101 b, 1-6 or 101, I, and 21 CFR 56.107, 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 Policy. Those components which can be expected to

participate in human participant research sponsored by DHHS or other Federal departments or agencies for which this Policy will apply are Howard University and Howard University Hospital.

D) This Policy must be accepted by other Federal departments or agencies that are bound by the Federal Policy for the Protection of Human Participants when appropriate for the research in question and therefore applies to all human participant research so sponsored. Research that is neither conducted nor supported by a Federal department or agency but is subject to the regulations as defined in 45 CFR 46.102, e, must be reviewed and approved, in compliance with 45 CFR 46.101, 102, and 107 through 117 and 21 CFR 56.