

Approved by the Board of Regents
on 02/02, 2021

MORGAN STATE UNIVERSITY

POLICY FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH

1. Introduction

This Policy for Protection of Human Subjects in Research (“Policy”) is for the protection of human subjects in research and related activities conducted under the auspices of Morgan State University (the “University”). The Policy also serves to ensure the University’s compliance with all applicable laws and regulations regarding research involving human subjects, which include the Department of Health and Human Services’ assurance of compliance, policies, and regulations referenced at 45 C.F.R. Part 46.

2. Applicability

This Policy applies to all research related activities involving human subjects and to all development, training, and improvement or other related activities containing a research and development component. Furthermore, the Policy applies to any such activity performed elsewhere by faculty, students, or employees under the auspices of the University, regardless of the source of funding or whether there is funding.

3. Policy

The policy of the University is to respect and safeguard the rights and welfare of individuals in the conduct of research. The University understands research to be a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research, whether or not they are conducted or supported under a program which is considered research for other purposes. Actions of the University will be guided, to the extent that they are applicable, by principles as set forth in nationally accepted documents such as the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Ethical Principles and Guidelines for the Protection of Human Subjects of Research (April 18,

1979). Actions of the University will also conform to applicable federal, state, and local laws and regulations.

In accordance with this Policy, all University research activities which involve human subjects, regardless of the level of risk foreseen, require review and approval, prior to the initiation of the activity. The University Institutional Review Board (IRB) shall have jurisdiction over all reviews and approvals in accord with procedures set forth in recognized documents, e.g. Federal Wide Assurance (FWA) and/or applicable regulations (45 C.F.R. Part 46).

University Official, who is deemed to be the President or designee (including but not limited to Vice President for Research and Economic Development and/or the Provost), may disapprove research that has been approved by the IRB. The University Official may also impose additional restrictions or stipulations to an approved study but may not amend the IRB's terms of approval or take any actions that serve to lessen any measures deemed necessary for protection of human subjects in research. However, the University Official may not approve research involving human subjects that has not been approved by the IRB in accordance with 45 CFR 46.112. Those research activities in which human subjects may be exposed to more than minimal risk must be reviewed at a convened meeting of the IRB; other research activities may be reviewed in the manner determined by the IRB under its procedures. A research subject is considered to be at more than minimal risk if exposed to the possibility of harm -- physical, psychological, social, legal, or other -- as a consequence of participation as a human subject in any research activity which departs from the performance of routine physical or psychological examinations and tests, or which departs from established and accepted procedures necessary to meet the individual's needs, or which increases the probability or magnitude of risks ordinarily encountered in daily life.

To carry out this Policy, the University will maintain an IRB with appropriate membership to provide for adequate reviews. The IRB will have the authority to approve, to require modification as a condition of approval, and to disapprove proposed activities that are covered by this Policy. Furthermore, the IRB will have the authority to determine whether or not any activity is covered by this Policy and whether it requires review by the IRB. The University may rely upon an external IRB for review and approval of research if (a) the University's responsible official, identified in its FWA, approves use of the external IRB and (b) the responsible official determines that the external IRB meets federal standards.