OP 79.03: HUMAN SUBJECTS IN RESEARCH

PURPOSE

The purpose of this policy is to provide for appropriate use of human subjects in research performed under the auspices of Mississippi State University.

DEFINITIONS

1. **Human subject** – a living individual about whom an investigator (whether professional or student) conducting research
    1) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

    2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

2. **Research** – a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research:
    1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

    2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting

during the course of an event or crisis that threatens public health (including natural or man-made disasters).

3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

3. **IRB**– MSU's Institutional Review Board for the Protection of Human Subjects in Research– the primary responsibility of this committee is to protect the rights and welfare of human research participants. The IRB oversees all non-Exempt research activities involving human subjects (i.e. Expedited and Full Board studies).

4. **Institutional Official** (IO) – the key University leader authorized by the President to act on the University's behalf, specifically committing the University to compliance with all requirements of the Code of Federal Regulations, 45 CFR 46, and other applicable federal regulations (e.g., FDA 21 CFR 50 and 56).

5. **HRPP** – Human Research Protection Program – the administrative unit which oversees all research activities involving human subjects and reviews all Exempt proposed research involving human subjects.

POLICY

Mississippi State University holds a federal-wide assurance (FWA 00000203, IRB 00000709) from the Office of Human Research Protection. Under this assurance, MSU must comply with 45 CFR 46. MSU chooses to limit this assurance to federally funded research; however, the regulations under 45 CFR 46, including all of Subparts B, C, and D, provide the practical basis for the review and approval of all research at MSU regardless of funding.

The Vice President for Research and Economic Development serves as the Intuitional Official (IO) and is responsible for enforcement of this policy. The IRB's and the HRPP's authority is granted by the IO. The IRB has the authority to act independently to bind all activities falling under their purview. Further, the IRB is the only entity delegated the authority to review all proposed research involving human subjects performed under the auspices of Mississippi State University. All research involving human subjects must be reviewed and approved by the HRPP/IRB prior to initiation of the research.

The HRPP/IRB has the authority:

1. To create specific procedures that relate to the operation of the program of human subjects protections.

2. To approve, require modifications to secure approval, or disapprove all research activities involving human subjects overseen and conducted by MSU.
3. To suspend or terminate HRPP/IRB approval of research not being conducted in accordance with the HRPP's requirements or that had been associated with expected serious harm to participants.
4. To observe, or have a third party observe, the consent process and the conduct of research involving human subjects.

No other University official or committee may approve human subjects research that has not been approved by the HRPP. Any attempt to inappropriately influence the HRPP will not be tolerated.

All researchers who plan to use human subjects in research must complete a training course on human subjects protections endorsed or sponsored by the Office of Research Compliance. Alternate courses may be accepted but only at the discretion of the HRPP Officer. Approval of an HRPP application will be withheld until all project personnel have completed the course. A refresher course is required every five years to remain eligible to conduct research using human subjects.

The HRPP may conduct for cause and not-for-cause audits to assure compliance. Failure to comply with federal regulations or HRPP policies and procedures will result in the initiation of an investigation. Findings and recommendations will be made by the HRPP or IRB and may include remedial action including the termination of the project and/or disqualification of the researcher from conducting any further human subjects research. The researcher should communicate directly with the HRPP to resolve any concerns that may arise regarding a specific IRB decision.

Any individual may file suggestions or concerns regarding MSU's HRPP, the Office of Research Compliance and/or HRPP administrative procedures with the IRB Chair, HRPP Officer, Director of Research Compliance, Vice President of Research and Economic Development, or other University official as appropriate.

REVIEW

This policy will be reviewed every four years, or as needed, by the HRPP Officer and the IRB Chair with recommendations to the Director of Research Compliance for transmission to the VP for Research and Economic Development.

REVIEWED BY:

/s/ Nichole Cobb 11/01/2019
HRPP Officer

/s/ Kari Babski-Reeves 11/04/2019
IRB Chair

/s/ Kacey Strickland 11/01/2019
Director, Research Compliance

/s/ Julie Jordan 11/08/2019
Interim Vice President for Research and
Economic Development

/s/ Timothy N. Chamblee 11/18/2019
Assistant Vice President and Director
Institutional Research and Effectiveness

/s/ Joan Lucas 11/21/2019
General Counsel

APPROVED:

/s/ Mark Keenum 11/26/2019
President