

BURRELL COLLEGE OF OSTEOPATHIC MEDICINE

STANDARD OPERATING PROCEDURES

Protocol Deviations and Violations		RSP.029.00
Effective Date	May 2016	
Last Revision/Review	07/26/2023	

1. Purpose/Scope

Purpose- This SOP defines the categories of non-compliance with respect to deviations by investigators from approved protocols and the responsibilities of IRB in resolving matters of non-compliance.

Scope- All Burrell agents and students involved in human subjects research.

2. Related Policy/Authority

45 CFR 46

3. Faculty/Staff Responsibilities

Responsible Official(s)- Authorized Institutional Official for Research, Institutional Review Board.

4. Definitions/Abbreviations

5. Procedural Steps

- 5.1 **Guidance:** Pursuant to its responsibilities, the IRB oversees and conducts continuing review of all research that it approves. The Office of Research assists the IRB by conducting periodic and for-cause audits of approved protocols. In the course of audits or routine IRB business, incidents of noncompliance with federal regulations by investigators may be identified and must be brought to the attention of the IRB. Incidents of non-compliance are reviewed by the IRB. The IRB plan for managing the violation or deviation will depend on the severity of the violation and determination as to whether the violation represented willful intent of the investigator. A plan will be developed for each incident of non-compliance and communicated to the investigator in writing. The IRB conducts further audits of the research if deemed necessary.
- 5.2 **Categories and Definitions of Non-Compliance:** The following categories may be used by the IRB in determining the severity of investigator non-compliance.
1. **Category 1: Non-Compliance-** Category Non-Compliance results from failure of an investigator or researcher to comply with applicable Federal Regulations or Burrell IRB Policies that did not result in an increased risk to a human subjects research participants.
 2. **Category 2: Serious Non-Compliance-** Category Serious Non-Compliance results from an action or omission taken by an investigator or researcher that would be viewed by the general research community as compromising the rights and/or welfare of the research subjects. Violations in institutional, state and/or federal guidelines may result in serious non-compliance. Examples include but are not limited to failure of the investigator to obtain IRB approval prior to initiation of research activities, notify the IRB of changes in approved procedures, obtain and/or document informed consent or notify the IRB of changes in the scope and/or intent of the study.

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3. **Category 3: Continuing Non-Compliance-** Category Continuing Non-Compliance results from patterns of repeated actions and/or omissions by investigator or research personnel that indicate lack of ability and/or unwillingness to comply with institutional, state, and federal policies. It may result in further IRB actions.

- 5.2 **Investigation of Non-Compliance:** The IRB or a designated subcommittee of the IRB is responsible for investigating all reported and/or discovered incidents of non-compliance in human subjects research. A written report is prepared that provides the following information and distributed to the full IRB for further discussion at a convened meeting. The IRB Chairperson may choose to convene a special meeting of the IRB that is outside of the normal meeting schedule.

The Final Report on Investigation of Non-Compliance will address the following general headings:

- I. Brief description of the incident.
- II. Statement of exactly what the IRB determined as the non-compliant items.
- III. Explanation of why the IRB believes that the incident did not comply with Burrell, state and/or federal regulations.
- IV. Action taken by the IRB as a result of the investigation (See section 5.3).

- 5.3 Actions that the IRB may take in response to non-compliance include the following. The IRB may choose to identify a single action or multiple actions.
 1. No action
 2. Suspension of Enrollment of New Subjects and/or Research Activities pending receipt and review of a response and plan of corrective action from the investigator
 3. Modification of the research protocol
 4. Modification of the information disclosed during the consent process
 5. Requiring that current participants in the student re-consent to continue enrollment in the study
 6. Auditing some or all of the investigator's active protocols
 7. Termination of the Research

3. Faculty/Staff Responsibilities

Responsible Official(s)- Authorized Institutional Official for Research, Director of Research, Institutional Review Board.

6. Reports/Charts/Forms/Attachments/Cross References

7. Maintenance

Reviewed on an annual basis by the Office of Research.

8. Signature

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Approved by	8/9/2023
Assistant Dean for Research	Date

9. Distribution List

Internal/External

10. Revision History

Revision Date	Subsection #	Summary of Changes	New/Cancellation/Replacement Procedure? (if applicable)	Approval Date
7/26/2023		Converted from May 2016 policy		8/9/2023