

# BURRELL COLLEGE OF OSTEOPATHIC MEDICINE

## STANDARD OPERATING PROCEDURES

<b>Institutional Review Board Case Report Guidance</b>	<b>SOP #: RSP.001.01</b>
Effective Date	5/23/19
Last Revision/Review	5/23/19, Reviewed 8/28/19, Reviewed 11/29/2021

### 1. Purpose

To document the procedures used by the Burrell College of Osteopathic Medicine Institutional Review Board to review and evaluate submissions for the use of case studies/reports.

### 2. Related Policy/Authority

The U.S. Department of Health and Human Services Regulations: 45 CFR 46; The HIPAA Privacy Rule; and BCOM Policy 8530, Human Research Program Statement of Compliance.

### 3. Faculty/Staff Responsibilities

Assistant Dean for Research

IRB Chairperson

### 4. Definitions/Abbreviations

Research means 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 SOP, whether or not they are conducted or supported under a program that is considered research for other purposes.

Case Report means a description of a single case or three (3) or fewer cases in situations where the investigator did not have any research intent at the time of the patient intervention. Case reports generally involve description of medical treatment in a patient or a few patients with a unique treatment, disease course, or outcome based on a retrospective review of medical records or they can involve a description of a unique diagnostic finding or uncommon presentation.

### 5. Procedural Steps

- 5.0** A case report is a description of a single case or three (3) or fewer cases in situations where the investigator did not have any research intent at the time of the patient intervention. A case report generally involves the description of medical treatment in a patient or a few patients with a unique treatment, disease course, or outcome based on a retrospective review of medical records. A case report may also involve a description of a unique diagnostic finding or uncommon presentation.

Case reports may be used by clinicians as a means of disseminating information to students and/or professional colleagues within the institution, at professional meetings, and/or through publication in the medical literature. This Standard Operating Procedure addresses the BCOM requirements for review by the BCOM Institutional Review Board.

### **5.1. IRB Requirements**

A case report does not meet the federal definition of research since it is a description of a clinical case and not considered a systematic investigation leading to the production of generalizable knowledge. The investigator is not required to obtain IRB approval for a case report provided that the identity of the subject is protected.

Specifically, the presentation of publication must not contain any of the HIPAA Protected Health Information (PHI) identifiers listed below:

1. Names
2. All geographical subdivisions smaller than a State, including street address, city, county, precinct, code, and their equivalent geocodes, except for the initial three digits of a zip code, if according to the currently publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
4. Phone numbers;
5. FAX numbers;
6. Electronic mail addresses;
7. Social Security Numbers;
8. Medical record numbers;
9. Health plan beneficiary numbers;
10. Account numbers;
11. Certificate/license numbers;
12. Vehicle identifiers and serial numbers, including license plate numbers;
13. Device identifiers and serial numbers;
14. Web Universal Resource Locators (URLs)
15. Internet Protocol (IP) address numbers;
16. Biometric identifiers, including finger and voice prints;
17. Full face photographic images and any comparable images; and
18. Any other unique identifying number, characteristic, or code (Note: this does not mean a unique code assigned by the investigator to code the data)

### **5.2. Procedure for Authors/Investigators**

5.2.1. Burrell College investigators who prepare a case report involving a single patient or three (3) or fewer patients may not need to undertake any interaction with the IRB, as this activity does not meet the federal definition of "research". Investigators may cite this SOP or contact the Office of Research & Sponsored Programs for documentation that IRB review is not required.

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- A. Burrell College investigators wanting their Case Report project assessed for compliance with this SOP may contact the Office of Research & Sponsored Programs.
- B. Specific authorization of the patient is not required for a case report involving three (3) or fewer patients the report does not contain any of the 18 HIPAA PHI identifiers.
- C. Investigators who wish to publish a case report containing PHI are required to obtain specific authorization of the patient or, of the patient's legally authorized representative if the patient is deceased, under legal age, or otherwise unable to consent. Such consent must be obtained in advance of submission for publication.

5.2.2. The review of medical/dental records involving four (4) or more patients constitutes "research" and requires IRB review and approval.

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

N/A

### **7. Maintenance**

Developed by Joseph N. Benoit, Ph.D., Assistant Dean for Research

Reviewed annually by BCOM Research Advisory Council

### **8. Signature**

Signature on File

12.3.2021

Assistant Dean for Research

Date

### **9. Distribution List**

BCOM Faculty, Staff, and Students

### **10. Revision History**

Revision Date	Subsection #	Summary of Changes	New/Cancellation/Replacement Procedure? (if applicable)	Approval Date
1	[e.g., 3.1]	Removed reference to BCOM and replaced with Burrell College		12.6.2021