

BURRELL COLLEGE OF OSTEOPATHIC MEDICINE

STANDARD OPERATING PROCEDURES

Case Report and Case Series		SOP #: RSP.001.02
Effective Date	5/23/19	
Last Revision/Review	3/4/2024	

1. Purpose

To document the procedures used by the Burrell College of Osteopathic Medicine for submissions of case reports or case series.

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

4. Definitions/Abbreviations

Case Report means a description of a single case or three (3) or fewer cases in situations where the author did not have any research intent at the time of the patient care. A case report is a detailed description of a clinical encounter with a patient. This may include a report of the symptoms, signs, diagnosis, treatment, and follow-up of an individual patient. Case reports usually describe an unusual or novel occurrence and as such, remain one of the cornerstones of medical progress and provide many new ideas in medicine.

Case Series includes a description of the characteristics and outcomes among a group of individuals with either a disease or an exposure (which can be an intervention) over a period of time and without a control group. If more than three cases are involved in the report, the activity will constitute “research” of which IRB approval is needed.

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.

5. Procedural Steps

- A. 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

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students and/or professional colleagues within the institution, at professional meetings, and/or through publication in medical literature.

- B. Burrell College students are required to identify a Burrell College faculty member as a mentor throughout the development of the case report. The Burrell College faculty's name must be included in the submission of the case report/series for academic review and approval by the Office of Research and Sponsored Projects (see Item E below).
- C. Format (please see Section 6 of this SOP for a cross-reference for writing a case report).
 - a. A case report may include a combination of the following components
 - i. Title page: conveys the focus of the report
 - 1. Author names and affiliations: Burrell College students should use their Burrell College affiliation details
 - 2. Abstract (if required)
 - 3. Key Words
 - ii. Body
 - 1. Introduction
 - 2. Case Report
 - 3. Discussion
 - 4. Comments
 - iii. References
 - iv. Relevant Figures
- D. Consent
 - a. Patient Consent
 - i. The College requires informed consent from patients for **ALL** case reports. The Office of Research and Sponsored Programs maintains a Consent Form for this purpose, see Office of Research and Sponsored Programs website for consent form.
 - b. IRB Consent
 - i. Burrell College authors 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". 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.
 - ii. The review of medical/dental records involving four (4) or more patients constitutes "research" and requires IRB review and approval.
 - iii. Some journals require a letter, or other acknowledgement, from an IRB prior to publication of a case report. Specifically, journals wish to know whether IRB approval was obtained or not required for the described case. The IRB Chairperson is able to provide clarification to the author and/or journal regarding this process.
 - iv. Burrell College authors wanting their Case Report project assessed for compliance with this SOP may contact the Office of Research & Sponsored Programs.
- E. Protected Health Information
 - a. The case report and the notes for the creation of the case report must **NOT** contain any of the HIPAA Protected Health Information (PHI) identifiers listed below. To be

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considered “de-identified”, **ALL** of the 18 HIPAA PHI identifiers must be removed from the dataset. Be aware that HIPAA Privacy rule protects PHI of deceased individuals for 50 years following the date of death.

- i. Names
- ii. 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.
- iii. 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;
- iv. Phone numbers;
- v. FAX numbers;
- vi. Electronic mail addresses;
- vii. Social Security Numbers;
- viii. Medical record numbers;
- ix. Health plan beneficiary numbers;
- x. Account numbers;
- xi. Certificate/license numbers;
- xii. Vehicle identifiers and serial numbers, including license plate numbers;
- xiii. Device identifiers and serial numbers;
- xiv. Web Universal Resource Locators (URLs)
- xv. Internet Protocol (IP) address numbers;
- xvi. Biometric identifiers, including finger and voice prints;
- xvii. Full face photographic images and any comparable images; and
- xviii. Any other unique identifying number, characteristic, or code (Note: this does not mean a unique code assigned by the investigator to code the data)

F. Required Academic Review and Approval

- a. All case reports/series involving a Burrell student as an author must undergo an academic review prior to presentation or publication. Academic review will be conducted through the Office of Research and Sponsored Projects. All case reports/series must be submitted via email to the Office of Research and Sponsored Projects for approval. The submission must include the faculty member’s name who mentored the student during the development of the case report/series.

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

Patient Consent Form (see College website)

How to Write A Case Report (see College website)

7. Maintenance

Office of Research and Sponsored Projects

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Reviewed annually by Burrell College Research Advisory Council

8. Signature

Approved By	3/4/2024
Assistant Dean for Research	Date

9. Distribution List

Burrell Faculty, Staff, and Students

10. Revision History

Revision Date	Subsection #	Summary of Changes	New/Cancellation/Replacement Procedure? (if applicable)	Approval Date
12.6.2021	All	Removed reference to BCOM and replaced with Burrell College		12.6.2021
3.4.2024	5	Provided greater clarity on process for case reports/series, consent of patient, PHI that cannot be used.		3.4.2024