Edward Via College of Osteopathic Medicine

Policy Order No: R016
Effective Date: October 1, 2019

VCOM Policy on Case Reports and Case Series

1. PURPOSE
The purpose of this policy is to define case reports and case series and if these activities meet the definition of research. The policy also references a Case Report / Series Determination Form to aid investigators who are trying to determine whether an activity falls in the realm of research involving human subjects.

2. DEFINITIONS
Case report: A case report is a detailed report of the diagnosis, treatment, response to treatment, and follow-up after treatment of an individual patient. Case reports may contain demographic information about the patient (i.e. age, gender, ethnic origin).

Case series: A case series is a group of case reports involving patients who were given similar treatment. Case series may contain demographic information about the patients (i.e. age, gender, ethnic origin).

Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Systematic Investigation: An activity that involves a prospective plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a question.

Generalizable Knowledge: Information is expected to expand the knowledge base of a scientific discipline or other scholarly field or study and yield one or both of the following:
- Results that are applicable to a larger population beyond the site of data collection or the specific subjects studied.
• Results that are intended to be used to develop, test, or support theories, principles, and statements of relationships, or to inform policy beyond the study.

Generalized conclusions: Research findings that can be applied to populations or situations beyond the study population.

3. POLICY
Case reports/series submitted for publication do not strictly meet the criteria for research. Although a case report/series may be illustrative, it does not meet the Federal Policy for the Protection of Human Subjects definition of research, which requires a systematic investigation and the intent to contribute to generalizable knowledge about a disease or condition. Instead, a case report/series is intended to develop information to be shared for medical or educational purposes; highlighting one or a few particular cases for purposes of demonstration rather than for purposes of drawing generalized conclusions. This kind of project is most appropriately classified as an educational activity.

VCOM policy; therefore, is that a case report/series is not research that must be approved by the IRB. To determine whether a case report or case series requires IRB review, an author should complete the Case Report / Series Determination Form and submit it to the IRB Coordinator for review.

VCOM does not consider the number of patients as a defining factor for whether or not a case series should be classified as research. Educational activities often involve discussion of the course of a group of patients. It is the use of statistical method such as subgroup comparison and test for prognosis factors that are the distinguishing features of a systematic investigation. In the absence of the basic elements of a systematic investigation of a scientific question, the case report/series project should be classified as an educational activity rather than research, regardless of the number of patients that form the basis of the discussion.

Some criteria that typically represent case reports/series versus research are listed below and also appear on the Case Report / Series Determination Form:

<table>
<thead>
<tr>
<th>Common Elements</th>
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<tbody>
<tr>
<td><strong>Case Report/Series</strong></td>
</tr>
<tr>
<td>Not a systematic investigation</td>
</tr>
<tr>
<td>Not meant to be a representative sample (not drawing conclusions)</td>
</tr>
<tr>
<td>Reported/published without attempting to draw broader/generalized conclusions</td>
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4. ACADEMIC REVIEW FOR VCOM STUDENT AUTHORS
All case reports/series involving a VCOM student as an author must undergo academic review prior to presentation or publication. Academic review will be carried out by the respective campus Associate Dean for Biomedical Affairs and Research. VCOM students must submit their case reports/series via email to their campus Associate Dean for Biomedical Affairs and Research for approval.
5. IDENTIFIABLE HEALTH INFORMATION

If a case report/series will contain information that directly or indirectly identifies a patient, the author is to contact the hospital/clinic Privacy Officer or designee and must attain authorization for the use of this identifiable information from the patient or the patient’s estate if the patient is deceased.

The HIPAA privacy rule sets forth policies to protect all individually identifiable health information that is held or transmitted. There are 18 HIPAA Identifiers that are considered personally identifiable information. This information can be used to identify, contact, or locate a single person or can be used with other sources to identify a single individual. When personally identifiable information is used in conjunction with one’s physical or mental health or condition, health care, or one’s payment for that health care, it becomes Protected Health Information (PHI).

- Name
- Address (all geographic subdivisions smaller than state, including street address, city county, and zip code)
- All elements (except years) of dates related to an individual (including birthdate, admission date, discharge date, date of death, and exact age if over 89)
- Telephone numbers
- Fax number
- Email address
- Social Security Number
- Medical record number
- Health plan beneficiary number
- Account number
- Certificate or license number
- Vehicle identifiers and serial numbers including license plates
- Web URL
- Device identifiers and serial numbers
- Internet Protocol (IP) Address
- Finger or voice print
- Photographic image - Photographic images are not limited to images of the face.
- Any other characteristic that could uniquely identify the individual

If a communication contains any of these identifiers, or parts of the identifier, such as initials, the data is to be considered “identified.” To be considered “de-identified,” ALL of the 18 HIPAA Identifiers must be removed from the data set. This includes all dates, such as surgery dates, all voice recordings, and all photographic images.

Be aware that the HIPAA Privacy rule protects individually identifiable health information of deceased individuals for 50 years following the date of death. If the case report/series will include any identifiers linked to living persons or involves accessing death records maintained by the State Registrar, local registrars, or county recorders, the project must be approved in advance.

6. DURATION OF POLICY

The VCOM Policy on Case Reports & Case Series established by the Institutional Review Board is effective as of the date above and shall remain effective until amended or terminated by the President and Provost.
This is a guide to help an investigator determine if an activity being conducted meets the criteria for a Case Report/Series. In most cases, such projects do not need to be submitted to the IRB for review. After completing this form, if there is any question whether your project meets the definition of human subjects research, you will need a formal determination from the VCOM IRB. Contact the IRB Coordinator to discuss your project in more detail (Debbie Geiger, dgeiger@vcom.edu, 540-232-8425).

Please see Policy R016: VCOM Policy on Case Reports & Case Series, for more information.

<table>
<thead>
<tr>
<th>If you answer “Yes” to any of the questions in this section, then your project is likely to be research and you need to submit an application to the VCOM IRB. However, please complete the remaining sections.</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The study is an activity that involves a prospective plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a question.</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>2. The study tests a hypothesis OR establishes clinical practice standards where none are already accepted/established.</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>3. The study identifies a specific deficit in scientific knowledge from the literature.</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>4. The study specifically defines an intervention and/or interaction and use of collected data and may include randomization of individuals to different groups.</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>5. The study may use qualitative or quantitative methods to make observations, make comparisons between groups or generate hypotheses.</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>6. The study employs statistical methods that primarily compare differences between groups or correlate observed differences with a known health condition.</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>7. The study draws conclusions about a broader population based on the reported cases.</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>8. The study may or may not put persons at risk.</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>9. The study is reported/published in a way that suggests broad findings or recommendations (findings that can be applied to populations or situations beyond the study population).</td>
<td>☐</td>
<td>☐</td>
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<table>
<thead>
<tr>
<th>If you answer “Yes” to any of the questions in this section, then your project is likely a case report or case series:</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The study is not meant to be a representative sample (is not drawing conclusions for a broader group) but presents a unique clinical case or cases.</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>2. The study is specific to subjects’ condition and/or treatments.</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>3. The study describes a diagnosis, treatment, response to treatment, and the follow-up after treatment of one or two patients.</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>4. The study describes the nature of diagnosis or treatment.</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>5. The study by design does not increase risk to persons, with exception of possible privacy or confidentiality concerns.</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>6. The study is presented to show unique clinical cases at professional meetings to medical students or to colleagues. The report/publication specifically notes case reports when presented or published in medical journals.</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>
If you determined that your project is a case report or case series answer the following question:

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
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</table>

1. The case report/series involves the collection and reporting of Protected Health Information (PHI). If yes, the author is to contact the hospital/clinic privacy officer or designee. For more information on the HIPPA privacy rule, please visit: https://privacyruleandresearch.nih.gov/pr_08.asp

There are 18 HIPAA Identifiers that are considered personally identifiable information:

- Name
- Address (all geographic subdivisions smaller than state, including street address, city county, and zip code)
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