**VCOM Institutional Review Board**

**Case Report/Series Determination Form**

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.

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| **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.** | **YES** | **NO** |
| 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. |  |  |
| 1. The study tests a hypothesis OR establishes clinical practice standards where none are already accepted/established. |  |  |
| 1. The study identifies a specific deficit in scientific knowledge from the literature. |  |  |
| 1. The study specifically defines an intervention and/or interaction and use of collected data and may include randomization of individuals to different groups. |  |  |
| 1. The study may use qualitative or quantitative methods to make observations, make comparisons between groups or generate hypotheses. |  |  |
| 1. The study employs statistical methods that primarily compare differences between groups or correlate observed differences with a known health condition. |  |  |
| 1. The study draws conclusions about a broader population based on the reported cases. |  |  |
| 1. The study may or may not put persons at risk. |  |  |
| 1. 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). |  |  |
| **If you answer “Yes” to any of the questions in this section, then your project is likely a case report or case series:** | **YES** | **NO** |
| 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. |  |  |
| 1. The study is specific to subjects’ condition and/or treatments. |  |  |
| 1. The study describes a diagnosis, treatment, response to treatment, and the follow-up after treatment of one or two patients. |  |  |
| 1. The study describes the nature of diagnosis or treatment. |  |  |
| 1. The study by design does not increase risk to persons, with exception of possible privacy or confidentiality concerns. |  |  |
| 1. 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. |  |  |

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| **If you determined that your project is a case report or case series answer the following question:** | **YES** | **NO** |
| 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) * 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 * Any vehicle or other device serial number * 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 |  |  |