Federal regulations define research as a systematic investigation designed to develop or contribute to generalizable knowledge. A case report/series which are not generalizable, do not qualify as research.

Case Report is a publication, article, presentation, or other public dissemination of information involving a retrospective review and description of routine medical care for a single patient. A case report has no hypothesis, no data analysis, and no generalizable conclusion.

Case Series is a group or series of no more than three case reports.

> A *case study* is a qualitative research method. It is an in-depth analysis, empirical inquiry, or investigation of a person or group in a natural, uncontrolled setting. This research method is done from the participants' perspective and studies how they make meaning of the world – not how researchers manipulate it. Qualitative researchers study things in their natural settings, attempting to make sense of, or to interpret, phenomena in terms of the meanings people bring to them.
>
> A case study includes multiple data sources such as interviews, documents, archival records, direct observations, and physical artifacts. Analysis is through description, themes, and assertations. Researchers from many disciplines (e.g., social/behavioral, educational, epidemiological) use this method to build upon past theory, produce new theory, and dispute current theory.
>
> A Case Study meets the federal definition of research and must be submitted to the IRB or review and approval.

Case Reports may consist of publications, articles, or presentations at conferences or in settings outside of the clinical, educational and research activities of CFVH. Conditions, diagnoses, treatment, and outcomes may be described in a Case Report/Series. Case Reports are intended to develop information to be shared for medical or educational purposes and not to add to "generalizable knowledge." A critical component is nothing was done to the patient(s) with prior "research" intent.

CFVH and HIPAA requires combined informed consent with HIPAA authorization to be obtained from the patient(s) for publication/presentation of a Case Report/Series. The author of the Case Report/Series must obtain the signed consent of the patient(s), or the patients' legally authorized representative if the patient is deceased, a minor or is cognitively disabled, to publish or present the information in a Case Report/Series.

The use of PHI to prepare the publication, article, or presentation does not require HIPAA authorization.

CFVH requires the patient's PHI must be de-identified, unless the patient has signed an informed consent which includes the identified information that will be used, such as but not limited to photographs and images, before a Case Report/Series can be submitted, published, presented, or disclosed in any manner.

If there are exigent circumstances and you have tried at least three times to contact a patient or their legally authorized representative to obtain a signed consent, you may conduct the case report/series. You are *required* have your abstract and written report/poster legally reviewed prior to submission/presentation/publication. You must also provide justification for not obtaining the informed consent.

To de-identify the PHI, 18 identifiers as described by the federal regulations and found in ***IRB***

Guidance: HIPAA and Human Subjects Research.

Note: One of the 18 identifiers is "Any other unique identifying number, characteristic, or code." For the purposes of a Case Report/Series, this would include a case so unique or unusual that it might be possible for others (including the patient) to identify the individual(s) (who is/are the subject of the Case Report.

In addition, HIPAA requires at the time of publication, "the covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is subject of the information."

Only Case Reports/Series abstracts and final written reports/poster presentations are required to undergo a legal review.

CFVH Investigators/Staff conducting a Case Report/Series do not need IRB determination or oversight unless an authoritative determination is required by a journal or conference for publication or presentation. *Only if an authoritative determination is required*, an ***IRB: NHSR Protocol Application Form*** must be submitted to the IRB with the abstract and final written report or poster presentation.

Investigators/Staff may always consult with the IRB Chair, Co-Chair, or IRB Administrator to discuss whether an activity does or does not meet the definition of research with humans any may require IRB oversight. The IRB cannot issue retroactive approval of an activity conducted as a Case Report/Series and is later determined to be human research.

Residents and Trainees conducting a Case Report/Series must submit:

1. **Consent Obtained**: a ***GME: Case Report/Series Project Form***, using the Wufoo form and attach the ***GME Investigator Agreement Form*****.** The GME Research Program Administrator for tracking purposes and acknowledgment. *Only if an authoritative determination is required* by a journal or conference prior to acceptance of a health care related manuscript or poster for publication or presentation, the Program Administrator will forward to the IRB Administrator.
2. **Consent Not Obtained**: a ***GME: Case Report/Series Project Form***, using the Wufoo form and attach the ***GME Investigator Agreement Form***, the abstract or written report/poster for legal review. The GME Research Program Administrator for tracking purposes, legal review, and acknowledgment. *Only if an authoritative determination is required* by a journal or conference prior to acceptance of a health care related manuscript or poster for publication or presentation, the Program Administrator will forward to the IRB Administrator.

Advisors, Residents, and students may always consult with the Research Administrator, Research Director, or IRB Chair to discuss whether an activity does or does not meet the definition of research with humans any may require IRB oversight. The IRB cannot issue retroactive approval of an activity conducted as a Case Report/Series and is later determined to be human research.

If you have further questions, please contact the Research/IRB Office at 910-615-5839 or sleming@capefearvalley.com.