

Resident/Student Research  
APPENDIX B  
Case Study/Limited Case Study

**Please review attached “Case Study/Limited Case Study Definitions/Guidelines” for an overview of relative information.**

**Prior to submitting request please ensure the following are included:**

- \_\_\_\_\_ **Completed Resident/Student Project Approval Request form (attached)**
- \_\_\_\_\_ **Project Description including all elements identified in the “Case Study/Limited Case Study Template” (attached)**
- \_\_\_\_\_ **Patient Consent (if applicable) including all elements identified in the “Template – Consent Form for Case Study/Limited Case Series” (attached)**
- \_\_\_\_\_ **Documentation of current research education for each investigator and protocol coordinator (One option for meeting this requirement is completion of Good Clinical Practice web-based training course (all modules) <https://gcp.nidatraining.org>).**

Resident/Student Research  
APPENDIX B  
Case Study/Limited Case Study Definitions/Guidelines

**DEFINITIONS:**

1. Case Study – a detailed examination of an event or series of events.
2. Limited Case Series – defined as no more than three case studies.

**GUIDELINES:**

Case studies/limited case series may be conducted by residents or students in conjunction with a faculty advisor. **NOTE: Publication of the results of a case study will require review and authorization by legal services (see attached template for additional detail).**

Projects that are thought to be a case study/limited case series are to be submitted to the CFV IRB for an authoritative determination of their status by using the “Project Approval Request Form”. As a result of this review, the submission will be declared to be exempt from further IRB review, or determined to be a research study involving humans that is subject to further IRB review. **NOTE: In the event of a rare disease where the study of 1-3 cases might produce generalizable knowledge, or in the event a particular case is sufficiently unique that it may be identifiable, the IRB may require full IRB review.**

The template presented below is designed for projects involving the detailed examination of an event or a series of no more than three events. Since the focus of these projects does not fit the definition of research under 45 CFR 46.102(d), they will be evaluated as not involving research with humans. For such projects, privacy and confidentiality regulations (HIPAA) must still be followed. The IRB will review and provide consultative assistance, but is not responsible for approving how privacy, data storage and confidentiality measures are implemented in the quality improvement project.

The project summary for the IRB should be no more than 5 pages. Please use the template below to complete the proposal. Please use the checklist on page 4 of this document to ensure all required documents are submitted.

Patient consent for a case study/limited case series is generally not indicated if:

1. The study meets the definition of “limited case series” (defined as no more than three case studies) and;
2. All 18 HIPAA requirements relative to removal of patient identifiers are followed and;
3. The circumstances of the case(s) are not so unique that the patient is identifiable  
**(NOTE: Consent may be required by the IRB regardless of the structure of the study or may be obtained at the discretion of the investigator).**

If any one of the above is not met, patient consent is required. (Consent form template is attached).

The final draft of a proposed publication related to a case study/limited case series should be submitted to the legal services office prior to publication. Approval by legal services is required prior to publication of information related to a case study/limited case series.

RESIDENT/STUDENT PROJECT APPROVAL REQUEST

**NOTE TO PI: Any publication related to this study will require approval by Hospital Legal Services prior to publication. Please contact Legal Services at extension 5937 for additional information.**

**Completed form and a summary of the proposed research should be returned via e-mail to Lenelle Davis at [ldavis@capefearvalley.com](mailto:ldavis@capefearvalley.com). For questions please contact Lenelle Davis at the noted e-mail address.**

Proposal Title: \_\_\_\_\_

Your Name: \_\_\_\_\_ Date: \_\_\_\_\_

Contact Information: E-mail \_\_\_\_\_/Phone \_\_\_\_\_

University/Residency Program Affiliation: \_\_\_\_\_

Name/Contact Information for Faculty Advisor/Attending Responsible for Oversight of Project:

Name: \_\_\_\_\_ E-Mail \_\_\_\_\_/Phone \_\_\_\_\_

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**Preliminary Determination:**

In compliance with policy titled "Resident/Student Research" I have made the following preliminary determination regarding the type of project being submitted:

- \_\_\_ Quality Improvement Project – Documentation as required in Appendix A is attached.
- \_\_\_ Case Study/Limited Case Series – Documentation as required in Appendix B is attached
- \_\_\_ Exempt Research (indicate specific category below) –Documentation as required in Appendix C is attached
  - \_\_\_ Retrospective Review (collection and analysis of existing medical record information; ordinarily seek to evaluate relationships between one or more biomedical, treatment, and/or demographic variables and one or more outcome measures in patients.)
  - \_\_\_ Case Series (greater than three case studies; a case study is a detailed examination of an event)
  - \_\_\_ Educational Survey – (includes evaluation of teaching sessions, curricula, courses, programs, simulations and surveys)
- \_\_\_ Non-Exempt Research – Documentation as required in Appendix D is attached

\_\_\_\_\_  
RESIDENT/STUDENT SIGNATURE

\_\_\_\_\_  
DATE

**FACULTY STATEMENT:** I confirm that I have reviewed this project proposal and approve for submission to the CFVHS IRB:

\_\_\_\_\_  
Faculty Member Signature

\_\_\_\_\_  
Date

\*\*\*\*\*

Date Proposal Forwarded to IRB: \_\_\_\_\_

Resident/Student Research  
APPENDIX B  
Case Study/Limited Case Series Template

**Title of Case:**

**Authors of Case:**

**Patient Consent (Is patient consent required based on stated guidelines [see above] or is it being obtained at the discretion of the investigator? If no, indicate N/A. If yes, attached proposed patient consent prepared utilizing attached template).**

**Summary (up to 150 words summarizing the case presentation and outcome):**

**Background (why you think this case is important – why you decided to write it up):**

**Case Presentation (presenting features, medical/social/family history):**

**Differential Diagnosis:**

**Treatment:**

**Outcome and Follow-up:**

**Discussion (similar cases in the literature)**

**Learning Points/Take Home Messages:**

**References:**

**Publication (indicate whether you plan to publish case study/limited case series. If yes, include The following statement on the submission “I understand prior to publication of information related to this proposal, review and approval by CFV legal services is required”).**

**NOTE: If publication is intended:**

- 1. Final approval by the IRB will be contingent upon receipt of approval for publication from Legal Services;**
- 2. Upon receipt of provisional approval from the IRB, a final draft of proposed publication (with copy of patient consent if applicable) should be submitted to Meghan Engle in Legal Services ([mengle@capefearvalley.com](mailto:mengle@capefearvalley.com)) for approval. Ms. Engle will issue notice of approval via return e-mail (allow a minimum of five business days for response).**
- 3. Notice of approval for publication, to include any changes as recommended by legal counsel, should be submitted to the IRB after which notice of final approval by the IRB will be issued.**

**Signature and Date of Submission:**

IRB Approved 7/19/18

Revised : 6/20/19

# CAPE FEAR VALLEY HEALTH SYSTEM

## Policy – Procedure

### Template - Consent Form for Case Study/Limited Case Series

Case Report: **Insert TITLE**

Principal Investigator: **Name, degrees held**  
**Institution**  
**Contact Phone Number**

Patient: **Name**

You are being asked to consider allowing Dr. **(insert name)** to use information about your **(insert condition/disease/experience)** to write what is called a case report. Case reports are typically used to share new unique information experienced by one patient during his/her clinical care that may be useful for other physicians and members of a health care team. A case report may be published **(in print and/or via internet dissemination)** for others to read, and/or presented at a conference. This form explains the purpose of this case report. Please read this form carefully and take your time to make your decision and ask any questions that you may have.

The purpose of this case report is to inform other physicians that **(insert specific reason i.e. patients presenting to the ER with X)** may be **related to Y, however, was masked by a common over the counter medication Z).**

Your information being used for this case report includes **(insert specific information here)**.

Dr. **(insert name)** is obligated to protect your privacy and not disclose your personal information (information about you and your health that identifies you as an individual e.g. name, date of birth, medical record number). When the case report is published or presented, your identity will not be disclosed.

Although your personal information collected or obtained will be kept confidential and protected to the fullest extent of the law, there is a limited risk associated with this case report that could result in a loss of confidentiality by virtue of your unique experience.

You will not directly benefit from participating in this case report. The information that can be shared with other health care professionals, however, may improve the care that is received by others in the future.

Allowing your information to be used in this case report will not involve any additional costs to you. You will not receive any compensation.

Taking part in this case report is your choice (voluntary). You may choose not to take part or you may change your mind at any time. However, once the case report is written and published, it will not be possible for you to withdraw it. Your decision will not result in any penalty or loss of benefits to which you are entitled including the quality of care you receive.

You will be told about any new information relating to this case report that may affect you.

Your signature below means that you have read the above information about this Case Report and have had a chance to ask questions to help you understand how your information will be used and that you give permission to allow your information to be used in this case report.

If you have any questions please contact **(insert name)** at **(910) XXX-XXXX**

**SUBJECT CONSENT TO PARTICIPATE**

## CAPE FEAR VALLEY HEALTH SYSTEM Policy – Procedure

Case Report **Title:**

Name of Participant: \_\_\_\_\_

Participant/Substitute decision-maker

By signing this form, I confirm that:

- The case report has been fully explained to me and all of my questions have been answered to my satisfaction;
- I have been informed of the risks and benefits, if any, of allowing my information to be used in this case report;
- I have been informed that I do not have to participate in this case report;
- I have read each page of this form;
- I authorize access to my personal health information (medical record) as explained in this form;
- I have agreed to participate in this case report.

\_\_\_\_\_  
Name of Participant/Substitute  
Decision-maker (print)

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date