Please read ***IRB Guidance: Case Report/Series Project*** prior to completing this form.

**DEFINITIONS:**

1. 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.
2. Case Series – defined as no more than three case reports.

**Instructions:**

* Case report/case series may be conducted by residents or students in conjunction with a faculty/staff advisor.
* Projects that are thought to be a case report/case series are to be submitted to the GME Research Program Administrator via email at [sleming@capefearvalley.com](mailto:sleming@capefearvalley.com) for review and tracking purposes. If you require an IRB letter of determination the Administrator will forward to the IRB for official determination. If you do not require an IRB letter of determination the Administrator will notify you via email if further clarification is required or the submission is acceptable.
* This form is 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(l), IRB review and determination is not required. For such projects, privacy, and confidentiality regulations (HIPAA) and Institutional policies must still be followed.
* Attach verification of human subjects training certification for all project team members. See ***IRB Guidance: Human Subjects Research Training*** to determine what training is required.
* Return completed (must have all signatures obtained) ***GME Investigator Agreement*** with this submission.
* Please ensure you have discussed your potential case report with your Faculty/Staff Advisor, Program Director, and the GME Research Director ***prior*** to submitting this form.
* *A draft or final draft of the proposed written case report presentation/publication must be submitted with this form to the GME Research Program for review by the Research Director and Legal Services. Once your final draft is approved. A copy of the GME approval will be sent to you via return e-mail (allow a minimum of five business days for response).*

**NOTE: Publication/Presentation of the results of a case report will require review and authorization by legal services (see attached template for additional detail).**

**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.**

**Consent:**

* Effective 1/23/2023, patient consent for a case report/limited case series is **required**. The GME Research Program recommends having the attached consent readily available for use as case reports are an unexpected occurrence (Consent form template is attached).
* **DO NOT SUBMIT SIGNED CONSENT FORMS!** Please retain all consent forms. Consents must be stored in the locked file drawer located in the Medical Education Building, FL 2, Research Lab Workroom.

**Fill-in Form Starts on Next Page**

|  |
| --- |
| **Submission Date:** Click or tap to enter a date. |
| Project and investigator Information |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Project Title: *Title* | | | | | | | | | | | | | |
| Faculty Advisor or Staff Responsible: | | | | Enter Name | | | | | | | | | |
| Rank/Title: | Rank/Title. | | | | | | | | Institution/Department: | | | Institution/Department | |
| Role/responsibilities in this project: | | | | Click or tap here to enter text. | | | | | | | | | |
| Preferred Phone Number: | | | XX-XXX-XXXX | | | **Institutional Email** | | | | Click or tap here to enter text. | | | |
| Medical Student/Resident: (if applicable) | | | Enter Name | | | | | | | | Program Year | | enter text. |
| University/Residency Program Affiliation: | | | | | Click or tap here to enter text. | | | | | | | | |
| Phone Number: | | XX-XXX-XXXX | | | | | **Institutional Email:** | Click or tap here to enter text. | | | | | |
| Clinical Site: | | | Click or tap here to enter text. | | | | | | | | | | |
| Case Study/Case Series | | | | | | | | | | | | | |
| 1. **Your written report/poster should include the following information sections:**  * **Introduction –** include background and why this case in novel and important * **Case Description-** description of the presenting features, etc. * **Discussion –** available treatment, treatment plan, extenuating factors, similar cases in literature, out come & follow-up * **Conclusions** * **References** * **Acknowledgements** | | | | | | | | | | | | | |
| 1. **Consent:**   *Do not attached the signed patient’s consent document(s).* Patient consent must be retained and stored as outlined in CFVH policies and procedures. Compliance and Legal Services may request to see the signed consent. | | | | | | | | | | | | | |
| Yes, informed consent was obtained using the attached consent document  Date Consent Obtained: Click or tap to enter a date.  No, informed consent was not obtained using the attached consent document. STOP. Patient consent is **required** to be obtained. | | | | | | | | | | | | | |
| 1. **Publication:**   *Upon completion of the case report/series, the draft of the proposed publication must be submitted to the GME Research Program for review by the Research Director and Legal Services. Once your draft is approved, notice of approval via return e-mail (allow a minimum of five business days for response).* | | | | | | | | | | | | | |
| Yes  If “yes,”  *I understand prior to publication of information related to this proposal, review, and determination by CFVH legal services is required.* | | | | | | | | | | | | | |
| 1. **IRB Determination:**   *Some publications and meetings require an official IRB letter of determination stating the case report is not human subjects research.* | | | | | | | | | | | | | |
| Yes, I require an official IRB letter of determination.  No, I do not require an official IRB letter of determination. | | | | | | | | | | | | | |

REMINDER: This Case Report/Series Form is to be emailed to the GME Research Program Administrator at [sleming@capefearvalley.com](mailto:sleming@capefearvalley.com).

**Case Report/Series Consent**

Name of person described in article: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Information/Photos Collected (list PHI): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Case Report/Series Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Medical practitioner or corresponding author & degrees: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Cape Fear Valley Health Location: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Phone Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

I\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [print full name] give my consent for this information about MYSELF OR MY CHILD OR WARD/MY RELATIVE [print full name]:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, relating to the subject matter above (“the Information”) to appear in a journal article, or to be used for the purpose of a thesis or presentation.

I understand the following:

1. The Information will be published without my name/child’s name/relatives name attached and every attempt will be made to ensure anonymity. I understand, however, that complete anonymity cannot be guaranteed. It is possible that somebody somewhere - perhaps, for example, somebody who looked after me/my child/relative, if I was in hospital, or a relative - may identify me.
2. I authorize access to my personal health information (medical record) as explained in this form.
3. The Information may be published in a journal which is read worldwide or an online journal. Journals are aimed mainly at health care professionals but may be seen by many non-doctors, including journalists.
4. The Information may be placed on a website.
5. I can withdraw my consent at any time before online publication, but once the Information has been committed to publication it will not be possible to withdraw the consent.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Participant/Legally Signature Date

Authorized Representative (print)

I have carefully explained to the subject the nature of the above project. I hereby certify that to the best of my knowledge the person who is signing this consent form clearly understands the nature, involved in his/her participation and his/her signature is legally valid. A medical problem or language or educational barrier has not precluded this understanding.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Person Obtaining Signature Date

Consent (print)