

**Case Study Governance Template**

A Case Study is an in-depth analysis and systematic description of one patient or group of similar patients to promote a detailed understanding of their circumstances. The illustrative 'grand round', 'case report' and 'case series' have a long tradition in clinical practice and research. Presenting detailed critiques, typically of one or more patients, aims to provide insights into aspects of the clinical case and, in doing so, illustrate broader lessons that may be learnt.

A record of all case study proposals should be compiled using the Case Study Governance template (Appendix A, below) and retained in Rio to facilitate audit. Where the Case Study is part of a student placement, a copy of the Governance template should also be signed and stored by the supervisor with all related documentation for the student on placement at the local site.

Case Studies which conform to the Trust’s standards (detailed in the Governance template) do not normally require assessment. However, where the author (or student supervisor) has question about the appropriateness of a proposal and specifically if an exception to Trust standard is being sought, the proposal should be submitted to the Trust’s Governance and Ethics Committee for Studies and Evaluations (GECSE) at elft.gecse@nhs.net

Confidentiality/Consent

It is important for the patient's privacy that the patient is not identifiable. This means that no details can be included that identify the patient, such as the name or anything unusual about that person or their case. We expect written consent of the service user to be obtained (see an example consent form at Appendix B, this can be adapted to suit your study) and stored in the patient’s case files. Any request for an exemption should be directed to the GECSE.

Individual consent is not required to write a case study / report about a group in general terms; this might include areas such as an overview of the demographics and clinical presentations of service users, and the interventions and processes used in the therapy. However, members of the group should be made aware that the group may be discussed and written about, and this discussion should be recorded in the standard group notes.

If the case study / report includes a focus on an individual within the group to explore clinical material in more depth, prior written consent must be obtained and recorded in the service user's medical record.

The Trust’s [Health Records Policy](https://www.elft.nhs.uk/uploads/files/1/Policies%20and%20Procedures/Information%20Governance%20Policies/Health%20Records%20Policy%20v2.1.pdf) states, under the heading of Research and Teaching that *“principles of access and confidentiality remain the same and the right of the patient to refuse access to their records should be respected and documented in their notes”* (page 9) and under Information Sharing that *“Explicit consent is required if identifiable service user information is used in any publication“* (page 8). This applies to equally to the work of trainees who have to follow the same principles as anyone else regarding [obtaining informed consent to use data in a study](https://www.elft.nhs.uk/Research/Conducting-Research/Consent-to-use-data).

Data security

The case study should be treated with the same care as the medical notes. All data, including the case study itself should be, maintained on ELFT computer systems. Under no circumstances should the case study be drafted on university computers or at the student’s home.

Publication and sharing

The final case study can be shared with the clinical care team and submitted to the student’s academic institution for course assessment. If the study will be shared more widely, particularly if it will be published, the proposal should be referred to the GECSE. Please advise the communications team of any article that is to be published.

**Appendix A: Case Study Governance form**

|  |  |
| --- | --- |
| **Title** |  |
| **Authors (e.g., student)** |  |
| **Academic Supervisor** |  |
| **Degree / training programme and HEI** |  |
| **In which clinical service is the case study set?** |  |
| **Case study of individual or group?** |  |
| **Will parts of the treatment record be included, e.g. Clinical data, x-ray, process notes, audio or visual recording, art-work, etc? If so, describe:** |
|  |
| **Will written consent be sought? If not, what is the justification?** |
|  |
| **How will details that identify a person be removed?** |
|  |
| **Where will the data, notes, drafts be stored (electronic and/or paper)?** |
|  |
| **With whom will it be shared and how will it be transmitted to these collaborators?** |
|  |
| **With whom will the final report be shared? Anyone external to the Trust?**  |
|  |
| **Will it be published? If so, where?** |
|  |

**Appendix B: Template Consent Form for use with Case Studies**



**Consent form**

I …………………………….………………………………..………….... [Name] give my consent for information about myself/my child or ward/my relative (circle as appropriate) to be published in …………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………… [Name of journal, manuscript number and corresponding author].

I understand that the information will be published without my/my child or ward’s/my relative’s (circle as appropriate) name attached, that the text will not disclose any details directly related to my person such as address/birth place, d.o.b., etc., but that full anonymity cannot be guaranteed.

I understand that the text published in the article will be freely available on the internet and may be seen by the general public. The text may also appear on other websites or in print, or may be translated into other languages.

I have been offered the opportunity to read the manuscript.

Signing this consent form does not remove my rights to privacy.

Name…………………………………

Date………………………………….

Signed………………………………..

Author name………………………..

Date…………………………………

Signed………………………………

Please keep this consent form in the patient’s case files. The manuscript reporting this patient’s details should state that ‘Written informed consent for publication of their clinical details and/or clinical images was obtained from the patient/parent/guardian/ relative of the patient. A copy of the consent form is available for review by the Editor of this journal.