MSF Consent form for Case Reports: Guiding Principles

The purpose of this consent form is to guide you through the steps which ensure that consent from a patient or a patient's guardian is truly *informed*.

Publication of a case report requires informed consent:

For the publication of a case report obtaining the appropriate informed consent from the patient (or his/her legal representative) is mandatory. There are cases when consent is impossible to obtain, still the case could be publishable, but you should contact an Ethics Committee to ask for guidance and assessment about the specific circumstances, before proceeding to writing the case.

Informed consent implies that the person has been able to make a conscious choice to accept or not accept the proposed intervention (in this case the publication of his/her medical case report). Therefore the **necessary comprehensive information** should be given around the objective, the content, the risks and benefits of the publication of the medical case report.

The consent has to be made in **a language that the patient (or his/her representative) understands** (using words that are culturally adapted and, in case of child assent, age-specific). If translation is needed (no written language), then it is important to ensure the translation reflects correctly what is in the information form.

The consent procedure should be done **in a room/space that permits full confidentiality,** and puts the person at ease without giving any impression of coercion. It should be made very clear that acceptance or refusal is completely **unrelated to the quality and extent of the care** that will be provided to the patient. Ideally the consent procedure should be done **by a staff member who is not involved in the care** to avoid the misconception of the implication on the level of care. Requesting informed consent is also better at the end of the care process (for example before discharge).

All should be done to obtain informed consent **before** the patient is discharged (or deceased). Contacting the patient (or his/her legal representative) after exit needs to be carefully considered as this can be an issue of breach of privacy of the patient (one does not want the community or relatives to know about attending health care or health structure admission) or even a breach in confidentiality (whenever the project is vertical for example). Contacting patients (or their legal representative) after exit is not problematic if consent was given to do so (example in a project where consent is given by the patient to be further contacted for results of tests or for attending follow up consultations). In case the patient has deceased, consent should be handled sensitively with relatives being encouraged to respect the deceased person's wishes (or in certain cases, their legal representative)

Who should give informed consent?

- The patient should give consent if in capacity to give informed consent (full consciousness, emotionally stable, no mental or neurologic impairment) and:
    - the patient is an adult (> 18yrs of age)
    - the patient is an emancipated adolescent[1] (the definition of this concept varies from country to country so you should find out what applies in the country where the patient is residing)
- The legal representative (parent or legal guardian[2]) whenever:
    - the patient is a minor (< 18 yrs of age)
    - the patient is not in capacity to give consent (temporarily or permanently; the circumstances when this will apply will also vary from country to country)
    - the patient is deceased

Children above the age of 7 years of age (7 is an arbitrary number and attention should be given to assessing the maturity of each patients to provide consent) should receive age and culture adapted explanations about the case reporting. They have to be given the possibility to ask questions and to give their assent; it is their agreement for their case report to be published. In case the child does not give his/her assent, the case report cannot be published, even if the parent (or legal guardian) has given consent.

How is informed consent documented?

The Consent Form is an official paper document that contains the essential information for which the patient (or his legal representative) gives consent and the name and signature of the person who is conducting the consent procedure. The Consent Form should be dated and signed by the patient (or his/her legal representative). In case the patient (or his/her legal representative) is illiterate, the consent can be oral as long as all the information is given to and understood by the patient (or his/her legal representative) and there is a witness signing that the patient (or his/her legal representative) has agreed and given his/her consent. The witness should be literate, understand the patient's (or legal representative's) language and not be part of the staff that directly managed the case.

What should be done if informed consent is no longer possible?

When the idea of a case report comes after a patient has been discharged (or died) and the patient (or his/her legal representative) can or should not be contacted, obtaining informed consent will not be possible.

Publication can still be possible but there is a need to conduct a risk-benefit assessment by an independent experience researcher.

Once all identifiers have been removed, an assessment needs to be done on whether the case report still has sufficient elements to be relevant.

[1] Emancipation is when a minor has achieved independence from his or her parents, such as by getting married before reaching age 18 or by becoming fully self-supporting.

[2] A legal guardian is appointed whenever a minor is an orphan or none of the parents are in capacity to (e.g. Out of the country, in prison, on duty, not competent etc.) to make care decisions or take care of a minor.

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Specifics around images:

Medical imagery (like X-Ray, Ultrasound, Scan, etc.) as well as pictures from the patient(s) or his/her environment can be very useful to illustrate a case report and reduce the number of words in the description. However images can be very identifiable.

For the patient's dignity, consent has to be requested before taking any picture/photo. Consent should include what exactly will be photographed and what use will be made of the picture/photo (including how long it will be stored and with whom it will be shared). This consent can be oral but should be documented in the medical file with the name of the person who obtained the consent.

Identifiable body parts and regions that are very intimate should be avoided as much as possible: only the specific topic/lesion should be photographed.

Beware that pictures/photos can include indirect identifiers like the surroundings or a date. In medical imagery often patient identification and some clinical data is included. Any kind of identifiable information that is in an image has to be removed as much as possible before it is shared or published.

Additionally, the use of any picture/photo or any medical imagery as illustration for a case report should be clearly notified to the patient (or their legal representative) and the image shown to him (or their legal representative) for approval. This has to be included in the consent form that the patient (or their legal representative) will have to sign.