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]](#footnote-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]](#footnote-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.

# 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 his legal representative) and the image shown to him (or his legal representative) for approval. This has to be included in the consent form that the patient (or his legal representative) will have to sign.

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| VÃ½sledek obrÃ¡zku pro msf logo | **Informed Consent Form for Publication of Case Report**  ……………………………………….. [Name of the author proposing the case report/series] |

You [*or your child or the person you legally represent*] has been treated at the …………………………… ……………………………………………………………………… [*Name of the health structure or medical program*].

The medical team that took care of you [*or your child or the person you legally represent]* believes that the medical condition you [*or your child or the person you legally represent]* have experienced and/or the way it was managed (diagnosis – treatment- follow up) as well as the outcome should be published.

This means that sharing the information around your case (but with removal of your name, address and phone number) could be important to help other medical staff understand the condition better and have a better management for other patients who experienced the same condition.

We would therefore ask your consent to make a report of your case that will be published in a medical journal.

What does this mean?

* The report will contain details on your disease *[or from your child or the person you legally represent*], the tests that were done, the medication and other treatment that was given, the effects of the treatment on the disease and on your body, the evolution of the disease and the result of the care you [*or your child or the person you legally represent]* received.
* The report will not contain your name *[or from your child or the person you legally represent*], nor the address, phone number, or other coordinates that would make it possible to directly recognize you.
* However, some details of you disease or the treatment you received might make it possible for some people to recognize that the report talks about you [*or your child or the person you legally represent].*
* Medical journals are read mostly by health care professionals and students. However, publication in a medical journal means that the report can be read by anybody who can have access to the scientific journal, either on paper, or via internet (computer), all over the world.
* If it is useful to add a picture of you *[or from your child or the person you legally represent*] in the report to better illustrate the condition, we will ask for your permission first and ensure you cannot be recognized on the image.

What are the benefits?

There are no direct benefits for you [*or your child or the person you legally represent].* There will not be any financial or other material benefits.

However, this might help future patients with the same conditions in your country but also in other countries. It will help to train health staff in better understanding the conditions you [*or your child or the person you legally represent]* had/have.

What are the risks?

The risks are related to the possibility that someone who reads the report recognizes you [*or your child or the person you legally represent]* and this can maybe cause you problems. This can be a relative or a health care worker or someone from your community or somebody else.

As your name, address, phone number will not be in the report, the chances are small that someone recognizes you, but it is not impossible. This is especially for rare diseases or remarkable events, and the fact that a case stands out is often a major reason to report it. We reinforce that any personal identifiable information will be removed.

What are your choices?

You can accept that the report of your case *[or from your child or the person you legally represent*] is published in a medical journal.

You can also refuse, and this will not make any difference for the further care you [*or your child or the person you legally represent]* will receive.

You can accept it and withdraw your consent at any time by contacting *……………………………………………………... [Name and contact details of the consent taker*] but only before the report is published. Once the report is published in the medical journal, it cannot anymore be removed.

How do you consent?

If you agree that a report of your case *[or from your child or person you legally represent]* is published in a medical journal, you can sign the form to confirm your consent. If you cannot sign, we will ask a witness to sign as a confirmation that you have given your consent.

If the patient is a child older than 7 years old, we will also ensure the child is given all the information about the publication of a case report and will ask the child if he/she agrees, in your [caretaker or representative] presence, if you request this.

You will receive a copy of the information we just gave you and the signed consent form.

MSF will keep a copy of the consent form for no longer than three years in a secured confidential place, under the responsibility of the Medical Coordinator. In the case of project or mission closure before the three-year period, the consent forms should be digitally scanned and stored online in a password-protected manner, under the responsibility of the respective Desk. After the three years period the consent forms will be destroyed. If the country where the consent form is obtained has an Ethical Body, their procedures will take precedence.

If you have any questions, please feel free to ask us, we will take the time to respond until you have received all the answers.

If you have any questions in the future, you can contact: ………………………………………………………………………….

*[Name and contact details of the consent taker*].

**CONSENT FORM**

**For a patient’s consent to publication of information and/or images about them in an online scientific journal and/or other means of dissemination such as research posters and conference presentations.**

*Name of patient:*

*Relationship to patient (if patient is not signing this form):*

*Description of the material (text, photo, image):*

*Provisional title of the material:*

**Consent**

I \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [PRINT FULL NAME] give my consent for the material specified above about me/the patient to be published in an online scientific journal.

I confirm that I [PLEASE TICK BOXES BELOW]

□ have seen any photographs or images to be included in the Case Report

□ have received a clear explanation of the content and purpose of the Case Report

□ am entitled to give consent

□ (if consent is for a child) have explained to my child aged 7 to 18 years what a Case Report is and received his/her assent

□ (if consent for a deceased person) have duly considered my deceased relative’s dignity and probable wishes

In signing this form, I understand the following:

1. The material will be published without my/the patient’s name or other potential identifier (e.g. address or phone number…); however I understand that complete anonymity cannot be guaranteed. Whilst every effort will be made to remove potential identifiers, it could happen that someone (e.g. a relative or healthcare professional) would recognize me/the patient.
2. The material may show or include details of my/the patient’s past medical history, medical condition, prognosis, treatment, and outcome.
3. The report may be published in a journal which is distributed worldwide. Medical journals are read mostly by health care professionals and students. However, open-access journals (publication on the internet) mean that anyone can potentially read the report and thus discuss it or replicate it (e.g. for teaching purposes).
4. I/the patient will not receive any financial benefit from publishing the Case Report.
5. I can revoke my consent at any time before the Report has gone to press, from which moment on this will be impossible.
6. This consent form will be retained securely by MSF and for no longer than three year, if no other procedures apply (details above).

[PLEASE TICK BOX BELOW]

□ I consent to MSF storing my contact details for the sole purpose of contacting me, if necessary, in the future (for example to clarify some aspects of the treatment received or for an update on how the experience of your care was)

*Print name:*

*Telephone number/ Email:*

*Address:*

*Date:*

*Sign:*

**Witness in case the patient (or legal representative) cannot sign:**

*Print name:*

*Telephone number/ Email:*

*Date:*

*Sign:*

**Details of the person has explained and administered the Informed Consent form:**

*Print name:*

*Position at MSF:*

*Address/Email:*

*Telephone:*

*Date:*

*Signed:*

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. [↑](#footnote-ref-1)
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. [↑](#footnote-ref-2)