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Publication of medical case reports and consent



The Committee on Publication Ethics (COPE) published guidance on consent for publishing medical case reports in 2016 [1]. Paragraph 26 of the Declaration of Helsinki version 7 2013 states the following [2]: 'In medical research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information. After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed. All medical research subjects should be given the option of being informed about the general outcome and results of the study.'

Being assured that consent has been obtained is important as journals need to know that the individuals or their legal representatives who give consent to publication have been:

- 1. adequately informed,
- 2. are aware that consent can be withdrawn without reprisal up to the point of publication
- 3. that people can be identified, even though names are not published.

The aim of this editorial is to summarise provide guidance regarding consent as an aid for authors submitting cases to Case Reports in Women's Health (CRWH).

The journal does not collect copies of signed consent forms so as not to breach confidentiality and patient information laws. However CRWH expects that copies of the consent form are retained by the treating institution as well as by the individual (and/or legal representative) whose case is being reported. CRWH does not provide a consent form but expects certain required elements are included in the consent form and may request a blank copy from institutions.

The key elements in the consent form are:

- 1. Name of the patient.
- 2. Name of the person signing the consent form. A legal representative may provide consent if patients are unable to consent (lack of mental or physical capacity, are under the legal age to provide consent, or are deceased). The legal age for providing consent varies between countries (see for example reference [3]) If a legal representative signs the consent form, the reason should be provided.
- 3. Assurance that the patient/legal representative has been informed that consent is being given for publication and current and future uses might be made of the report. Furthermore that consent can be withdrawn before but not after publication.
- 4. Consent forms should indicate that consent does not remove the patient's rights to privacy. However, by their nature, there is a risk that patients may be identified from the case report.
- 5. Forms should specify whether or not the patient or their legal representative has seen the final version of the case report to be published (including pictures). If a final version has not been shown, it must be clear what the patient or proxy has seen and that he or she has agreed to publication without having seen the final version of the article.
- 6. The name and contact details of the person who obtained consent. They should be suitably qualified and authorised to do so in their institution.

Provenance and Peer Review

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Contributors

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Conflict of Interest

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Margaret Rees, Stephen L. Corson' Women's Centre, John Radcliffe Hospital, Oxford OX3 9DU, UK Case Reports in Women's Health, United States E-mail address: margaret.rees@st-hildas.ox.ac.uk

^{*} Corresponding author.