Case Reports in Women's Health 36 (2022) e00449

Contents lists available at ScienceDirect

Case Reports in Women's Health

journal homepage: www.elsevier.com/locate/crwh

Invited Editorial

Researchers, authors and consent

ARTICLE INFO

Keywords
Consent
Authors
Publishing ethics

It is widely acknowledged that research into healthcare is vital. The treatments that are offered to patients today are based upon the research undertaken by many healthcare practitioners and researchers, often over many years. However, the importance of research does not override an individual's right to choose whether to participate or not and the level of any participation.

Consent is a vital aspect of the healthcare research process, such that the World Health Organization has produced templates that researchers can use in designing their own research. These have two elements to them, an information sheet and a certificate of consent [1]. This allows for pertinent information to be provided to prospective participants and for the researcher to have a record of the individual's consent to participation.

Given the importance of consent in the research process, it is a requirement that all articles published in *Case Reports in Women's Health* can demonstrate that appropriate consent, relevant to the country where the research was undertaken, has been obtained from any individuals involved in the research or where their information is being included, including images [2].

Potential authors can assist themselves, and the *Case Reports in Women's Health* editorial team, by ensuring that they do not commit one of the recurring consent issues that can result in a rejection of the article or a delay in its publication.

Lack of Consent

As already noted, having relevant consent from participants is essential to being published in an ethically alert journal. Whilst an author is not required to supply the consent with their manuscript, they do need to confirm that the consents have been obtained and are available if necessary. If the relevant consent cannot be confirmed, it is not possible for a journal such as *Case Reports in Women's Health* to publish the manuscript.

Age-Appropriate Consent

Article 1 of the United Nations Convention on the Rights of the Child states that a child is someone under the age of 18 [3].

Legal requirements for consent in relation to children vary across countries and legal jurisdictions, dependent upon when and how a child reaches legal competence [4]. As an example, within the United Kingdom there are two legal criteria for obtaining consent from individuals under 18, depending upon which country of the United Kingdom the child resides.

In many jurisdictions a child is unable to consent for themselves and consent needs to be obtained from a parent, guardian, or someone with legal responsibility for the child.

A further consideration in relation to child patients as participants in research or with using the information of a child in a publication is that of the child who is pregnant. Some countries treat a pregnant child as being emancipated and so able to make their own decisions independent of their parent or legal representative. This means that the child would be able to provide their own consent to participate in research or for their details to be published.

A failure to have the appropriate consent in relation to a child can mean that a manuscript is rejected for ethical reasons. It is therefore important to ensure that when seeking consent for those under 18, it is sought from the appropriate person.

Consent for Purpose

There is a difference between treating a patient and recording details of the treatment in their health record and publishing details of a patient's treatment [5]. When a patient agrees to have a specific treatment, they are not also agreeing to have the details of their condition and treatment published.

What this means for authors is that having a consent form for treatment signed by a patient does not suffice as consent for publication. Authors need specific consent from patients for their details to be included in the paper before it can be accepted for publication.

https://doi.org/10.1016/j.crwh.2022.e00449
Received 8 September 2022; Accepted 9 September 2022
Available online 13 September 2022

Treating the Patient and Authoring a Paper

There are many issues in deciding who should be listed as an author on a paper, for some of these see [6]. These will not be discussed here expect one: where a paper is discussing the care and treatment of a patient or group of patients, at least one of the authors should have been involved in the care and treatment of those patients.

The reason for this is that it is possible to read the health records of a patient or group or patients and write a paper based upon the information but never to have seen the patient and so never to have obtained consent from the patient for their personal information to be shared in a publication. Indeed, the patient may be unaware that their information is being used in this way.

Having at least one of the authors being clinically involved with the patient's care and treatment helps alleviate concern that appropriate consent has been obtained from the patient.

Death of the Patient

Although valid consent may have been obtained from the patient for their information to be published, if the patient dies before publication it should be confirmed with the patient's family or legal representative that publication will not be distressing to the family or cause any other harm to the deceased, their reputation, or their family.

Conclusion

Consent can be a difficult aspect of the publication process and if not obtained appropriately can lead to the rejection of a manuscript. Following the guidance above will hopefully make it less likely that a consent issue results in rejection of an interesting paper.

Contributors

Marc Cornock is the sole author of this editorial.

Funding

No funding from an external source supported the publication of this editorial.

Provenance and peer review

This editorial was commissioned and not externally peer reviewed.

Conflict of interest statement

The author has no conflict of interest regarding the publication of this editorial.

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