COMMITTEE ON PUBLICATION ETHICS

Discussion document on Best Practice for Consent for Publishing Medical Case Reports

COPE welcomes feedback on this document and we encourage journal editors and publishers to comment. Please email all comments to Natalie Ridgeway, COPE Executive Officer at http://publicationethics.org/contact-us

Introduction

The reporting of case reports is a common practice in medical journals and now, increasingly, in more basic science journals if they illustrate a specific scientific point (e.g., a genetic phenotype). There is no doubt that case reports are valuable in the academic literature. However, they pose a specific ethical challenge for journals because, unlike any other type of article, by their very nature the individual(s) in the paper is highly identifiable and hence journals must ensure that proper consent for publication (which is not the same as consent for a medical procedure or for enrolment in a trial for example) has been obtained and that the individual(s) who is being reported on is aware of the consequences of that reporting.

At previous COPE meetings we have raised the possibility of having a single case report form for journals to adopt, but after discussion it became clear that no one single form would serve the purpose of all journals. We therefore agreed to lay out the principles that a consent form should generally include and to collect examples of sample forms so that editors can develop a form that suits their purpose.

We welcome feedback on this discussion document until 31 March 2016 after which it will become a formal guidance document. In particular we welcome examples of good practice in case report forms, which we will link to.

Further, we hope that contributions to this discussion will help COPE identify guidance that would be beneficial for scholars in the social sciences and humanities, beyond the biomedically oriented discussion outlined here. We note that in social sciences and humanities there are numerous practices. For reference, some of these are described in sections 4.2 and 5.1 of the **Wiley ethics guidelines (http://exchanges.wiley.com/ethicsguidelines)**

Reference
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General Principles

1. Journals should not themselves collect the signed consent forms (because the receipt and maintenance of confidential patient information could subject them to cumbersome security requirements and potential legal liability under applicable privacy or patient information laws, such as HIPAA in the USA). Hence, journals should make the blank copy of the form available on their website and get authors to attest that it, or a form which includes the elements in the form, has been signed by the patient or their proxy.
2. Consent to publish forms should be used for any case where an individual or a group of individuals could be identified. Examples include descriptions of individual case histories, photos, x rays, genetic pedigree.

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Specific points forms should include

1. The forms should include a place for the name of the patient and the name of the individual signing the form. If these are not the same individual, the relationship of the signer to the patient must be stated. If one person is signing for a family, that person should attest that other members of the family have been informed.
2. The form should include a place for the name of the person who has explained the form to the patient and/or family member (this will usually be the individual reporting the case, but might be another individual, for example, curators of disease registries). This person must have the authority to obtain consent (i.e., be the senior clinician responsible for the patient's care or their delegate).
3. Forms should indicate that the patient has seen a version of the case report to be published (including pictures) and that they agree to it.
4. Forms should make it clear that the journal cannot guarantee confidentiality once the case report is published, even if every effort is made. This is especially true if the case is published freely online.
5. Forms should make it clear under what license the case report is published and hence what further use might be made of it.
6. Forms should indicate that signing the consent form does not remove the patient's rights to privacy.
7. Forms should indicate that the patient has been informed that they may revoke consent at any time before publication, but once the information has been published revocation of the consent is no longer possible.
8. It should normally be clearly stated that patients cannot expect to derive any financial benefit from publication of the case. Alternatively, if there is some financial benefit to the patient, that should be clearly stated on the form.
9. Ideally the form should be available in multiple languages as appropriate to where articles are submitted from.

Examples of cases report forms and relevant guidance

1. PLOS Journals: http://journals.plos.org/plosone/s/file?id=8ce6/plos-consent-form-english.pdf
2. BMJ Journals: http://journals.bmj.com/site/authors/patientconsent/consentenglish.pdf
3. BMC Journals: http://resource-cms.springer.com/springer-cms/rest/v1/content/6621850/data/v1/Consent-Form-PDF
4. Medwave (Spanish): http://www.medwave.cl/medios/Editorial/Formularios/Autores/FCIP-2015.doc
5. Wiley ethics guidelines: http://exchanges.wiley.com/ethicsguidelines