

# Legal and ethical requirements for developing a medical MOOC: Lessons learnt from the Paediatric Physical Examination Skills MOOC

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Massive open online courses (MOOCs) are increasingly being integrated into medical education. The production of a MOOC demonstrating physical examinations of children raised the issue of legal and ethical consent for the use of images and video-recordings of children. The present article shares the valuable lessons we learned around the legal and ethical consent required, and the operational issues that will be essential to comply with these legal and ethical considerations. This information may be valuable to other educators, especially those in similar resource-constrained settings, who are planning to create medical MOOCs.

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The growing interest in integrating massive open online courses (MOOCs) into medical education<sup>[1-3]</sup> is likely to increase during the current COVID-19 pandemic because of safety concerns for medical students being taught around the bedside. MOOCs typically consist of any combination of videos, images, slide presentations, assignments, computer-graded quizzes, and discussion forums.<sup>[4,5]</sup> Originally designed to provide learning opportunities for students who might not otherwise have access to higher education,<sup>[6]</sup> MOOCs are increasingly being developed for use in combination with face-to-face teaching (blended instruction<sup>[7]</sup>), which is the preferred way of integrating technology-enhanced learning into medical education.<sup>[8,9]</sup>

The Paediatric Physical Examination Skills (PPES) MOOC is part of the **Open-Access Paediatric Technology Assisted Learning (Open Petal)** project funded by the Discovery Fund since 2018. This project, undertaken at the Chris Hani Baragwanath Academic Hospital (CHBAH), was conceived as a teaching and learning resource to supplement face-to-face bedside paediatric teaching. The ultimate aim is to improve child health outcomes in resource-limited settings. The MOOC was conceptualised as a means of addressing the clinical teaching burden at CHBAH, the largest of four teaching hospitals affiliated with the University of the Witwatersrand (Wits). The problems encountered in clinical teaching at CHBAH, including large student groups at the bedside<sup>[10]</sup> and a lack of teaching resources,<sup>[11]</sup> are likely to be present in other resource-limited settings.

Of the 34 paediatric-related courses hosted on the MOOC platforms edX, Coursera, Udemy and Futurelearn, none of them as of December 2019 teaches paediatric physical examination skills. In our PPES MOOC, the issue of legal and ethical consent became a critical consideration because the MOOC would include recordings (photographs and videos) of ill children to demonstrate pathology. It is worth noting that any reproduction of a child's image, irrespective of the presence or absence of illness, requires ethical consent. We were unable to find any open source or university-approved

consent form that documents legal or ethical consent for medical MOOCs. The project team (two paediatricians from CHBAH, an educational expert, and the MOOC development team from the university's Centre for Learning, Teaching & Development) therefore conducted a series of workshops with a representative from the university's legal office, which led to the development of a consent form that meets the legal and ethical requirements in our setting (Appendix 1: <http://ajhpe.org.za/public/files/1412-1.pdf>). The lessons we learnt during the preparatory phase and the operational considerations essential to comply with the required legal and ethical considerations may be valuable to other educators who are planning to create medical MOOCs. We have summarised these lessons in Fig. 1.

## Lessons for developing a legally and ethically compliant consent form for the use of recordings of children in an online training course

While there are guidelines for obtaining informed consent and ethics clearance from an ethics board for paediatric research,<sup>[12]</sup> there is none for teaching purposes. A consent form for the use of recordings of children by health professionals in an online training course (consent form) should meet the following criteria for legal and ethical compliance.

### Clearly define what the requested consent is for

In terms of the South African National Health Act of 2003,<sup>[13]</sup> a patient is required to provide informed consent for all medical treatment. Accordingly, the consent form requests permission for the use of recordings by health professionals for teaching and learning purposes, including in the MOOC and iterations thereof.

Acknowledging that varied recording methodologies may present different burdens to the child and that obtaining a satisfactory image

## Guidelines for using clinical recordings of children in online training courses

### A. Development of the consent form: legal and ethical considerations

- Clearly define what the requested consent is for
- Specify who needs to provide consent
- Protection of confidentiality
- Give consentor(s) and children the right to review the recordings
- Make provision for the withdrawing of consent
- Include permission from the hospital/ health facility
- Obtain all required signatures

### B. Operational issues

- Determine who is responsible for obtaining consent
- Obtain video-release forms from the hospital and educators
- Maintain the confidentiality of recordings
- Prepare extensively for all recordings
- Uphold intellectual property rights and copyright
- Promote the protection of data
- Monitor the compliance of the use of digital images

Fig.1. Guidelines for the using clinical recordings of children in online training courses.

may require several attempts, the consent form requests permission for more than one photograph or recording, where necessary, on the understanding that every effort will be made to minimise the duration of photographing and recording and the discomfort to the patient.

### Specify who needs to provide consent

Many children in the areas served by the CHBAH (and elsewhere in South Africa) are cared for by extended family members or family friends who may not be the child's legal guardian or have any recognised legal relationship to the child.<sup>[14]</sup> Section 32 of the Children's Act No. 38 of 2005<sup>[15]</sup> allows a person who cares for a child voluntarily without formal parental responsibilities, to consent to medical (but not surgical) examination and treatment on that child's behalf. A caregiver can thus provide consent for the use of the recordings in the MOOC. The consent form provides for a parent, legal guardian, or caregiver [the consentor(s)] to consent to clinical recordings of 'my child/my dependent/my ward' [authors' emphasis].

There are no clear guidelines relating to a minor consenting to have their photograph taken or to be video-recorded, and whether such consent is legally binding. Snyman<sup>[16]</sup> recommends obtaining consent from children as young as 7 years of age to record their image. In clinical research, children aged 7 - 18 years are required to assent to participate in research studies.<sup>[12]</sup> In line with these

requirements, the consent form allows children aged 7 - 18 years to write their names or sign assent, where possible.

### Protection of confidentiality

As required by the Health Professions Council Of South Africa,<sup>[17]</sup> in accordance with the Promotion of Access to Information Act of 2000,<sup>[18]</sup> the National Health Act of 2003<sup>[13]</sup> and the Protection of Personal Information Act of 2013,<sup>[19]</sup> the consent form includes several clauses aimed at protecting the child's confidentiality. The consent form states that all reasonable precautions will be taken to preserve the child's anonymity and privacy. These precautions include removing facial features (wherever possible) and other distinguishing features from recordings or disguising them using pixelation. The consent form also includes a line drawing of a human body (as used by Snyman<sup>[16]</sup>), where the consentor(s) can indicate which features should be hidden in the edited footage (Appendix 1: <http://ajhpe.org.za/public/files/1412-1.pdf>). The consent form further states that all recordings will be stored on an off-line drive at a secure site.

The dissemination or duplication of digital images is difficult to prevent. As pointed out by Marshall,<sup>[20]</sup> 'privacy, anonymity, and confidentiality on the internet are increasingly fraught with challenges.' It is therefore vital that informed consent acknowledges that all reasonable precautions will be taken to preserve anonymity and privacy.

### Give the consentor(s) and the child the right to review the recordings

The consent form allows consenters to be present during the recording. The consentor(s) and/or children will be able to view the raw and edited footage, on request. Requests to view the recordings will be facilitated, since consenters and children in resource-limited settings may not have access to the internet or be digitally literate.

### Make provision for the withdrawing of consent

Children and consenters may request that recordings are deleted from the MOOC at any stage. A register matching recordings to individuals will be kept so that recordings can be removed if consent is withdrawn. The register will be securely stored in a site separate from the secure storage of the clinical recordings.

### Include permission from the hospital/ health facility

We obtained blanket written permission from the Chief Executive Officer (CEO) of the hospital for the project. This information is disclosed in the consent form.

### Obtain all required signatures

The consent form must be signed by the consentor(s), the child, the doctor(s), a translator (if used) and an independent witness. Anticipating that some consenters may not be literate, the consent form provides for consenters to use their thumbprint if they are not able to sign.

### Operational issues

In addition to developing a legally and ethically compliant consent form, the following operational issues are required to fulfil the legal and ethical obligations.

### Determine who is responsible for obtaining consent

The doctors leading the project will obtain informed consent, and no recording will happen prior to obtaining consent. Footage that does not contain a legible version of the signed consent form as the first photograph or 10 seconds of any video, will be deleted. Including the signed consent form in the footage will: (i) facilitate matching names to images during the editing process, so that metadata can be added that will allow the correct footage to be located if consent

is withdrawn; and (ii) serve as a check for videographers that they are allowed to continue filming.

## Obtain video-release forms from the hospital/health facility and educators

Educators are required to consent to their appearance (photographs and videos) being used in the MOOC. This form is available as Appendix 2 (<http://ajhpe.org.za/public/files/1412-2.pdf>). The hospital or health facility needs to sign a video-release form for material recorded on the hospital premises. In our case, the blanket permission we obtained from the hospital includes permission to release the videos.

## Maintain the confidentiality of recordings

All recordings will take place in a private space at the hospital to maintain patient confidentiality and minimise disruptions to clinical services rendered in resource-limited settings. All non-clinical personnel present during recordings must 'understand and agree to adhere to medical standards of privacy and confidentiality,'<sup>[21]</sup> as enshrined in South African legislation. These medical standards pertain to not divulging patient information and safe record-keeping of patient information. Clinical images will be recorded in a non-intrusive and discreet manner, and framing shots will exclude the child's identifying features. Every precaution will be taken to avoid sharing edited footage online.

## Prepare extensively for all recordings

Cognisant of the need to minimise the burden placed on children, all recordings will be extensively planned. Additionally, the training of clinical personnel in video-recording techniques will facilitate efficient recording. All members of our team were trained by a videographer to understand better the techniques to be used.

## Uphold intellectual property rights and copyright

The applicable policies of an institution govern ownership of material created within an institution. Such material must be protected from unauthorised usage and appropriately acknowledged when used outside the institution. The PPES MOOC will be released under the terms of Creative Commons Licence Attribution – Non-Commercial-ShareAlike 4.0 (CC BY-NC-SA 4.0).<sup>[22]</sup>

The South African Copyright Act<sup>[23]</sup> provides that copyright in recorded material vests in the creator. For example, at Wits university, staff and students are bound by the provisions of the university's Intellectual Property Policy,<sup>[24]</sup> in terms of which the university owns all intellectual property developed or originated by staff and students in the course and scope of their employment or studies. All consultants employed on the project to record photographs or videos will be required to assign the copyright in all recordings made on the hospital premises to the university.

## Promote the protection of data

All secure digital (SD) cards from digital cameras must be returned to a locked facility at CHBAH or the university immediately after a recording session. Recordings will be stored on an external drive that will be kept in a secured facility at the university. Recordings may not be retained by a staff member, or saved, backed up or transferred online. Editing of recordings will occur in private, secured workspaces.

## Monitor the compliance of the use of digital images

There needs to be an appropriate institutional mechanism in place for dealing with ethical or legal complaints arising from the use of digital images in online courses. For example, the integrity of the project could be reviewed by an independently appointed quality control team.

## Conclusion

We believe that the production of medical MOOCs and online courses will accelerate in response to the training of undergraduate and postgraduate students during the COVID-19 pandemic. Numerous legal and ethical challenges were encountered during the planning of our medical MOOC, especially as it involves children. We embarked on an unfamiliar process to resolve these concerns, and we hope that the lessons we learned prove helpful to other educators intending to produce medical MOOCs. Some of the lessons we have shared may need to be re-evaluated if any additional legal or ethical concerns arise. During the current pandemic, appropriate measures (including the use of personal protective equipment and social distancing) will be taken to ensure the safety of children, their parents/guardians/caretakers, doctors and filming crew.

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