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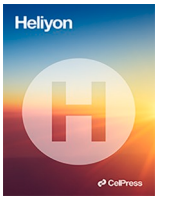

Research ethics, consent and publication

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1. Introduction

Whilst many authors fully comply with ethical requirements regarding the use of human subjects in research, there are a considerable number of authors who do not appear to understand the importance of ethical requirements or the principles which need to be followed, particularly with regard to consent.

The aim of this editorial is to outline the importance of ethical requirements in the publication process and some of the main principles which need to be addressed in order for a manuscript to fulfil the necessary ethical requirements and not be rejected because of a failure to meet the requirements.

2. Ethical considerations

As well as knowing that the research in the articles they publish is relevant, rigorous and robust, publishers also need to know that the authors have undertaken the research according to strict ethical principles.

The need for an ethical approach to research may be said to stem from the Nuremberg war trials which ultimately led to the Nuremberg Code. The Nuremberg Code is concerned with research on human participants, and it sets out a number of principles that researchers should follow for their research to be considered to be ethically valid.

In 1964 the World Medical Association published the Declaration of Helsinki, a set of ethical requirements relating to clinical research with human subjects. The guidance is periodically revised and updated. The current version is the tenth and was published in 2013. All versions of the Declaration of Helsinki, including the one currently in force, are available on the World Medical Association website [1].

The Declaration of Helsinki is an important document because it has been adopted by several countries as the basis for their own codes of ethics for research.

1974 saw the National Research Act become law in the United States of America. One aspect of the Act was the creation of a national body to oversee biomedical research. This resulted in the publication in 1978 of the Belmont Report, or to give it its full title, Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Report Of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research [2].

The Belmont Report outlines 3 key ethical principles when undertaking research using human subjects. These are: respect for the person, beneficence and justice.

There are various ethical frameworks that can be utilised by researchers to guide their research, and ensure that the rights of

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participants are respected, and ethical values are upheld. For instance, the World Health Organization has a Research Ethics Review Committee that reviews research applications to the WHO as well as liaising with individual countries on their ethical standards [3]. Different countries may have ethical frameworks that reflect the cultural and political approach for their own country. This means that the framework in one country is similar to frameworks in other countries but also distinct from them. The framework and standards in different regions of the world can be accessed at the [4].

Within a country there may be different research codes for those who work in clinical practice and those who work in academic settings. Although it would be expected that these will have the same principles at their core. In the United Kingdom for example, there is a research framework for researchers who work in the National Health Service [5] that are distinct from that which applies to researchers who work within universities.

Depending upon the country in which the research is being undertake, researchers may have to apply to a Research Ethics Committee (REC) to receive approval for their research study. The system in some countries may require that the researchers apply to more than one REC as each REC will have a specific jurisdiction. For instance, if a university researcher intends to conduct research on hospital patients int England, they would have to apply to the REC for their university as well as the REC for each hospital they intended to undertake the research. If the co-researchers were from different universities then it is usual for them to have to apply to the REC for each university where a co-researcher was employed.

There have been attempts to have a common platform for the ethical assessment of research. One project was the European SATORI (Stakeholders Acting Together On the ethical impact assessment of Research and Innovation) [6]. However, at present these common approaches have not removed the requirement to satisfy national RECs and regulations on research.

One point to remember about ethical codes is that they usually are not legally binding or a part of national laws, and whilst they are used to govern the practice of research with human subjects, this means that any applicable national law relating to research, for instance the self-determination of a person, also have to be adhered to for research to be ethically sound.

It is expected that all ethical frameworks will utilise the 3 key ethical principles from the Belmont Report and have the person at their centre. This ensures that the person who is being subjected to the research can have their self-determination upheld and be a willing participant in the research, or where this is not possible due to the type of research that their rights are protected.

A key aspect of self-determination is the right to consent for oneself and to decide what happens to your own personal information.

Consent

Consent can be said to be the legal mechanism that allows individuals to exercise their ethical right of self-determination. Different countries have different requirements for consnet to be seen as legally valid. However, most will require that the person who is providing consent is competent to do so, has the relevant information upon which to make their decision, and is making their choice voluntarily.

If one of the required criteria is missing then the consent given will not be legally valid and so cannot be relied upon and so cannot be relied upon for publication purposes.

Common difficulties with regard to obtaining consent for publication is the patient's competence and their understanding of what is being asked on them, the information they have been given and whether they are able to understand it.

The age at which a person may be able to give their own consent varies across countries. People under the age of 18 are defined as children by the United Nations [7]. In the United Kingdom, once a person reaches the age of 18 they are automatically presumed to have the competence to provide their own consent. If a patient 18 or over is not considered to have competence this would have to be proved by the health care practitioner utilising specific tests.

In the United Kingdom a person under 18 is treated in one of two ways according to whether they have reached the age of 16 or not. If they have had their 16th birthday they are treated as an adult ad do not have to prove their competence. However, if the patient is under 16, before they are able to give their own consent, they have to demonstrate that they are competent. This means that they can show that they have the emotional and intellectual maturity to make a decision.

If a patient is under 18, parents are able to give consent in the United Kingdom on behalf of the child. Thus, if a child under 16 is unable to demonstrate their competence a parent can be asked to provide consent in place of the patient.

3. Therapeutic versus publishing consent

There is a difference between consent that is provided for therapeutic interventions and that which is required for the purpose of publication. If a patient gives their consent to have a specific intervention, such as surgery, there does not mean that the health care practitioner who is treating them is able to use that consent to include the patient's details in a publication.

Consent is time and purpose specific. The fact that a healthcare practitioner is treating the patient does not allow them to go being the purpose for which the patient has provided their consent. This means that if a healthcare practitioner is intending to use a patient's personal information in a publication, consent needs to be obtained from the person concerned (for example, the patient) for that purpose.

Although there are some instances when consent is not needed directly from a patient. These include when the patient's information is being used after it has been anonymised and it is no longer possible to identify the patient from the data that is being utilised. Examples of research that use anonymised data can include chart review, audit and service evaluation [8].

Consent does not generally need to be given in writing. However, if a researcher is aiming to publish their research this may be at a point sometime in the future, and it may be difficult to prove that a patient has given verbal consent. Therefore, in order to comply with

the ethical requirements of a publisher it is good practice to have a written or electronic record of consent provided by patients in accordance with local legislation. However, it is important to note that some patients may have the capacity to consent but cannot record their consent in a written format, for instance patients who are paraplegic and those individuals who are illiterate. A signed consent form that details precisely the information that the patient has been given and what they have been asked to consent for is considered best practice, where possible.

This does not mean that consent forms should be submitted along with the manuscript to the publisher, nor necessarily that the publisher will need to see the consent forms, just that the author needs to provide confirmation to the publisher that valid consent has been required.

There are in a fact few occasions when a publisher would ask to see the consent forms. It would be an exceptional circumstance for a publisher to request the consent forms, most likely if there was an issue that the publisher needed to consult their legal services about [9].

4. Who should obtain consent

The ideal situation is that one of the health care practitioners who is treating the patient asks the patient for their consent for them to participate in a research study and for their personal information to be used in a publication.

The reason for this is that it is entirely possible to obtain a patient's information about a therapeutic intervention from the patient's health care record without actually having seen or treated the patient. This means that the patient may not be aware of what is happening with their personal information or the purposes that it is being used for.

Having at least one of the authors of a paper involved in the care and treatment of a patient mitigates this possibility, from both an ethical and publishing perspective, and provides protection for patients against their information being used without their consent.

5. Information needed for consent purposes

When a patient is being asked to consent for their information to be included in a research study and a subsequent publication there are certain areas of information that they should be made aware of so that they can provide an informed decision.

A patient can expect to be told what personal information they are being requested to share beyond what is necessary for therapeutic purposes; who their data will be shared with and for what purposes; whether it is anticipated the research will be disseminated and by what method e.g. publication in an international journal or conference presentation etc; how they can withdraw from the research and whether they can have their data 'forgotten' or removed entirely from the research study, and by what date this is necessary for their information to be removed from the research dataset; what will happen to their data at the end of the research study; and, how the data will be protected, both during the research study and after it has concluded and during the publication process.

6. Ethical committees and review bodies

There is a requirement that all researchers who undertake research on human subjects receive favourable approval from an appropriate ethical committee or ethical body that is able to review the proposed research and give recommendations on whether a patient's ethical rights are being protected.

An appropriate ethical committee will be dependent upon what research is being proposed, where the research is to be conducted and who will be undertaking the research. It will be one that is relevant to the research that is being proposed. For research involving patients this may be the institution that oversees the therapeutic environment or a university ethics review body that has oversight of the healthcare practitioners who will conduct the research.

Ethical committees will provide their findings and recommendations in writing and may require some changes to a research proposal before they give approval for the research to commence. Many ethics committee will provide a unique number for the research when it is approved. If there is a number it is useful to include this when submitting a paper for publication so that the approval process can be determined and checked if necessary.

7. Publishing requirements

Publishers are required to ensure that the papers they publish have met the necessary ethical requirements. This is so that they can fulfil their ethical responsibilities to protect patients and to the wider community.

By only publishing research that has been undertaken in accordance with an ethical framework such as the Declaration of Helsinki is part of ensuring that patients are not subject to unethical research. If researchers are unable to publish research that does not meet ethical requirements they may be less inclined to conduct such research and more likely to propose and conduct research that is protective of a patient's ethical rights.

Specifically, publications such as Heliyon need to know that the patient has provided their consent specifically for publication. A failure to be able to confirm this will usually mean that the manuscript will not be accepted for publication. Unless the type of research undertaken falls within one of the exceptions mentioned above.

If a publisher is not convinced that author(s) have followed the required ethical processed they will ask for clarification but if this is not forthcoming or does not address the concerns the publisher has the manuscript will be rejected.

Ensuring that ethical requirements are integral to the undertaking of the research itself and the preparation and submission of the

manuscript helps ensure that a paper is not rejected on ethical grounds.

Declaration of interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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