Review Article

# WASP (write a scientific paper): The ethical stages of publishing a research paper

**ABSTRACT**

**Background:** Authors have to be aware of the ethical stages in writing a scientific paper in order to be cognizant of what is required of them as researchers. The research ethics committee concerns itself with patient protection and therefore looks closely not only at the protocol, but also at the informed consent process and data protection issues. Conversely the publishers has ethical issues of their own relating to their reputation in publishing ethically sound and justified studies.

**Materials/Methods:** The article describes the ethics required of the research by looking at documents and directives which describe the ethical duties of the research, the functions of Research Ethics Committee and Publishing Ethics.

**Results:** The Researcher should be familiar with the informed consent process and data protection for research and the requirements of the research ethics committee. The informed consent process involves discussion of the research, the risks, the requirements from the patient/ participant and issues related with data protection. The second stage is that of the research ethics committee. This committee reviews the proposal and protocol of the research and any updates after the research approval. RECs are much concerned with the informed consent process and what is to be said to patients/ participants. Any precautions or arrangement for vulnerable groups should be identified. RECs move according to research ethics guidelines and are objective in their response. The final stage is the ethics of publication. The editor of a journal must ensure that ethics review has been made and ascertain as much as possible any conflicting or competing interests on the part of the researcher/s. The issue of identity of reviewers of the paper is also discussed.

**Conclusion:** The ethics of publication involves various ethical stages, each having their own responsibility towards patients and the scientific community.

**Key words:** Data protection; informed consent; publication ethics; publisher; research; research ethics; research ethics committee

The Ethical stages of publishing a research paper

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This paper reviews publication ethics which is taken to mean the ethical process a paper must go through before it can be submitted for a publication. Normally, no paper is accepted by reputed editors unless it has been through ethical review of a Research Ethics Committee (REC), and therefore, the process is described also in relation to what an REC expects from the principal investigator (PI) making the application for ethics approval. The paper is divided into three sections for clarity – that of the PI, that of the REC, and that of the publisher.

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## The Researcher

RECs today may be seen as a stumbling block for researchers. However, the scientific community encourages proper ethical review in order to maintain public trust. Experiments in the past have given rise to concern, trials, and document in relation to research. Unfortunately, abuse continued even after the first codes (Nuremberg and Helsinki) was formulated. In many instances, the consent process was not in order, and there have been patients on whose samples research was being done, who did not know.

Today, most countries have data protection laws. These usually specify what is already within the context of other laws, but as the information age makes access to data easier, and with the technological access to private information more easily available, these laws are continuously updated. Thus, it is usually not enough for a researcher to say that information and results will be anonylized. One must explain whether these can be accessed by a code (especially if information was obtained from a sample that is being kept) in which case it is said to be pseudo-anonymized. Moreover, one has to assert whether someone may be contacted in case of an incidental finding, in which case this should be explained to potential research subjects.

### Informed consent process

I elaborate on the process of consenting in a previous article.[1] However, the main concern is that in research, the process becomes a little more binding than in medical practice. Thus although exemption may be given for research done in an accident and emergency department, obtaining consent from someone with mild dementia, even if the answer is consistent, is not enough for research purposes (while it may be enough for treating a patient) and a proxy must be involved.

The information given to research subjects is one of the most important factors that is seen by the REC. The amount of information one gives to a patient follows a "reasonable person standard" when providing care. Although it has been shown that a reasonable person standard can vary from country to country,[2] in medicine, it is understandable that one cannot give all the details of treatment and therefore following an accepted practice (within a country) of what reasonable people would want to know about side-effects, risks, etc., is the usual procedure. In research, a reasonable person standard is not enough. One has to give details of the research in a manner that potential participant can understand. One can say that one has a "reasonable standard" for research. Therefore, many doctor researchers will recruit patients from their practice. Although in the past this was done during the consultation, this used to take a few minutes at most. This is not acceptable any longer and can only be considered sufficient in order to inform the patient about the research and if the latter answers that they are interested to make an appointment with a health-care professional who will explain the full details of the research. Usually, a period of 1 h is important to describe the research, explain to the patient what is required from him or her, explain their rights, and also the obligations of the researchers. Moreover, patients will usually be interested in knowing about the results and whether the research is stopped for any reason. Time has to be given for the patient to think about, reflect, and read any material provided.

Following the information-giving process, one has to make sure the patient has understood. Consent can only be given to be competent patients and the consent process will involve signing a document which has to be explained thoroughly again. One has to make sure that a voluntary choice is made – this can be compromised by coercion, manipulation, or persuasion. All three carry significant weight for the researcher. It is not so much that one coerces or manipulates the truth, which usually occurs, but the omission to recognize the legal meaning of these terms. Thus, a person who feels that he will disappoint his or her medical team if they do not participate in the research is being inadvertently coerced. The person making the interview must be responsible to the PI (who is ultimately responsible) to detect any character traits which may arose suspicion that the patient fears not participating. It may be expedient to ask whether they fear that by not participating they will be compromising their care, rather than merely to point out that their care will continue as normal if they refuse. In the same way, manipulation can occur if one omits to give relevant material. Although all the information given was true, an omission does constitute a breach not only of a reasonable person standard but also a manipulation of the overall picture. The gravity increases with the nature of information omitted such as the patients' rights, or the risks involved.

### Data protection

As described, data protection is being reviewed continuously. Data protection laws usually have exemption for medical, statistical, and historical purposes. This cannot be interpreted broadly in health care and is taken to mean that for the care of patients, doctors may share information with staff. This is to show the patient that confidential information may be shared with those concerned with the treatment. This obviously does not involve research and the ample EU projects on research and data protection are witness to this.[3,4] If a law does not specify something (in this case research), it does so for a reason. The definitions of the terms will usually attest to this. Data protection laws will usually provide a possibility to obtain exemption from the data protection commission, if contacting patients or relatives is not feasible.

Data protection is becoming an issue with biobanks. Can one give a broad consent for research to be carried out on his or her sample without giving them information about what the research is about. On the one hand, it does not make sense, to say the least, to go through such a thorough process for the type of research mentioned above and then to merely brush it aside when using sample from biobanks because a broad consent has been given. On the other hand, people do give their samples altruistically and may not really mind about the nature of the research. However, they may have objected had they known that (in the future) the research was to be done on a subject that they have a moral objection too. In this case, we use the same reasoning that we did for coercion and manipulation; by not giving at least some information and a means on how it may be obtained, one is simply assuming that the patient does not really care in cases in which a reasonable standard would assume that they in fact *do* care. Patient give samples because they trust the science community and one must show them that science cares, which is why they insist on giving some information. The process of obtaining consent is still under debate but a promising process is that of obtaining a *dynamic consent* in which people can log into, for example, a site and see what research is being carried out or being proposed and have a means to opt out of a particular one. The same system can be used to inform people about the state of the research.

## The Research Ethics Committee

The primary function of an REC is to safeguard the rights, safety, and well-being of research subjects. It asserts

1. investigator qualifications
2. protocol and any changes or amendments
3. written informed consent forms and any changes during the research
4. written information to be given to the subjects
5. investigator's brochures
6. available safety information
7. patient compensation
8. other materials that affect patient safety and willingness to participate.

The REC must have all the information therefore about the research project in order to be able to make an assessment. This includes all the literature and reasons, which led to the research being done in the first place. In general, one must provide the following:

1. Detailed protocol
2. Specify that investigators should not deviate from or change the protocol without prior written approval *unless* it is necessary to eliminate hazards or to change minor administrative details
3. Informed consent and recruitment
4. Protection of personal data
5. Description of measures to protect subjects
6. Require prompt reporting to REC of:
    a. Deviations from protocol
    b. Changes which increase any risk or conduct of research
    c. Any adverse reactions that are serious or unexpected
    d. New information that may adversely affect safety or conduct

The protocol should contain

1. Title, date, any sponsor information, PI/medical expert, and supporting institutions
2. Name and description of investigational product or research that includes prior studies and information related to safety, risks, benefits, dosing, route of administration, and length of trial
3. Description of target population
4. Relevant literature to population
5. Statement that research will be conducted in accordance with protocol and GCP (EC) standards
6. Trial/Research objectives and purpose
7. Research/Trial design
8. Selection and/or withdrawal of subjects and their treatment
9. Efficacy parameters and methods of assessing
10. Safety parameters ad methods of assessing
11. Statistical methods, significance levels, and criteria for research termination
12. Data management, quality control, ethics, and other administrative and proprietary understandings
13. Detailed description on subject recruitment including methods and processes to obtained informed consent, with special regard for any vulnerable groups/persons and persons who cannot give consent
14. Declarations on the use of genetic material, human tissue, and xenotransplantation.

The informed consent, data protection, and scientific validity are of the main concern. Often, there may be separate scientific committees. RECs usually have protocols and cannot refuse research, which is legal if someone on the board disagrees with it. However, the transcripts of the informed consent process should be given due attention. In general, what is going to be said to patients and a translation, if necessary, should be produced with the application. In addition, the actual consent form (plus translation) which patients will be required to sign has to be included. Data protection is given due consideration and one should state clearly how this is going to be managed and how it is going to be explained to patients. Usually, a statement that any data protection law will be adhered to is

important and reassures the committee, which, after all, in many legislations, takes on legal responsibility.

*Vulnerable groups* are given particular importance. Details on proxies for children, people with psychiatric illness, elderly who cannot give assent, etc., have to be provided. The REC is interested in how a legal and ethical consent is to be obtained and that there is no (even unintended) abuse or perception thereof. In many legislations, the ages 16–18 are given more rights and freedoms. However, notwithstanding these laws, parents often remain the legal guardians until the age of 18 and therefore they may have to give their approval for research. Of course, this may pose problems in certain questionnaires, which discuss drug abuse or sexual practices. It is only the REC that can give exemption if the law allows and if the study is seen to be important.

## The Publication

Editors are concerned about other ethical issues relating to what they publish. This is obviously done not only for the ethics of research itself but because they have the name of the publishing house to protect. Any breach and they will withdraw the article and perhaps the researcher tainted.

It goes without saying that publishing is based on trust.[5] Wiley have written a set of guidelines for authors and publishers. Transparency is one of the main issues. There is general agreement that publishers need to know:

1. Who funded the research
2. Do the authors have any conflicting or competing interests; if necessary what are they being paid
3. Did the funder have any input or role
4. Other sources of support
5. Who did the work: There ought to be a list of individual contributors, and what they did (this need not be put on the article itself but naturally has to be stated to the publisher
6. Has the work been published before? This can be also done within the writing of the article as references. However, it is unacceptable if an article, which appeared in a local journal, is submitted to an international journal without disclosure. The article may still be deemed important to publish once the requisite permissions are obtained
7. In writing the article, one assumes research integrity – that there was no plagiarism, fraudulent behavior, misconduct, fabrication, etc.

Moreover, authors are responsible to distinguish between ethically prohibited and ethically permitted language, with due respect to individual, countries, and cultures. These are issues that are ethically required; others may be ethically encouraged. Should a person who contributed to the grammar/correction of the article be included as an author? I personally have had this occur to me twice. One is asked by a PI or an editor of an issue of a journal to contribute an article. Later, you are told that someone made some corrections and ask to be put down as authors. Whilst one can find issue with this one leaves it to the editor, often goes unnoticed. Stating the contribution of each of the authors will help the editor assess the authors. Sometimes, one sees articles with over 20 authors and wonders what contribution each gave.

There has to be a minimum of work that one does in one particular research. It is unacceptable – and this is where publishers may fail the research community – that you see a number of articles with the same authors, with the first author sometimes changing from article to article. This of course raises the suspicion of collusion, knowing the importance of having one's name on as many papers as possible. When authors share workload, it is only acceptable to be an author if the work being done is significant and surpasses an acceptable threshold. This is not the remit of the REC (as yet) as this body sees the application before the research is done. It is the obligation of the publisher, who of course is making a profit off research, to participate in the protection of research integrity and the scientific community. However, the researchers should beware of this current "accepted practice" since, if concern is raised, so will public scrutiny and distrust ensue, endangering the trust, which we all cherish. Publishers ought to request the input from each author and see whether it is acceptable. Translation or corrections without addition of intellectual knowledge certainly do not have a place amongst the authorship.

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### Conflicts of interest
There are no conflicts of interest.

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