Publication Integrity and Ethics

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General P.I.E. Guidelines: Research integrity and ethics

Practice Guidelines

Please read the declaration at the end of this document before applying these guidelines

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Introduction

Research can be defined as the practice of testing new hypothesis through the acquisition, analysis, and systemic examination of qualitative and/or quantitative data. Research also aims to uncover new information, and must always be performed for the overall benefit of humanity and with ethical integrity. Underpinning this process is the consideration of sensitive political, social, ethical, legal, and cultural aspects in the surrounding environment of where the research is performed. When combined, these factors are the fundamental ethical fibres of the research domain, imbuing it with both its integrity and moral value. In learning and understanding these principles, researchers are expected to foster ethical actions and integrate them into their everyday working lives.

Research may require human participation in clinical trials, intrusive data collection, or the use of bio-hazardous chemicals or agents. It is therefore vital that all researchers adhere to a series of pre-determined, fundamental stipulations that govern both behaviour and expected conduct. Whilst there are many separate disciplines of research each with their own specific guidelines and procedures, there are some stipulations which are relevant throughout. The guidelines outlined in this document are for all professionals actively involved in the research process; here P.I.E. highlights the core principles of good research practice. Only in an environment whereby ethical practice is both defined and promoted, can a determined standard of integrity be cultivated. P.I.E. therefore advise all research professionals to have a working knowledge of these guidelines and to pass them on to their colleagues, particularly new staff members who are embarking upon their research career.

General principles

1 *Good practice guidelines for ethical research*

1.1 Researchers must adhere to all pre-set stipulations and legislative procedures governing their behaviour and conduct when engaged in research. Research should never aim to cause pain or damage, and is to be performed for the benefit of humanity.

1.2 Researchers of all disciplines are to remain honest and ethical in every area of their working lives. If at any point they discover a co-worker infringing upon any pre-determined ruling or guideline, they are to report it to the relevant authority at once.

1.3 Research data must be recorded accurately and with precision, taking the most finite details into consideration. As a general rule, research staff should have notebooks to hand at all times ready to document any important details.

1.4 No researcher should ever proffer fabricated or manipulated data in the published results of a research project. Such actions lead to breaches of public confidence as well as possible risk to the surrounding environment. Instead, all data must be disclosed with complete accuracy.

1.5 All data sourced from a research project must be taken into account in the final report. Omitting data for the expedience of a hypothesis statement is bad practice and should be avoided.

1.6 Researcher's must ensure their work is performed with due regard for cultural, religious, societal, and political sensitivities. It is these considerations which imbue the research domain with ethical integrity, a vital requirement of any serious researcher regardless of their field.

1.7 All research projects must aim to reduce the level of risk to its absolute minimum. Where possible, research involving human trials should recruit test subjects who may benefit from the research, although some studies (for example early phase 1 drug trials) specifically seek healthy subjects.

1.8 Research projects must go through a rigorous planning and design phase which should be ratified by an ethics committee review. The funding allocation that is outlined in the design must also be consistent throughout the study.

1.9 All research organisations, as well as the staff that work for them, should be open about their sources of funding. Under no circumstance should financial considerations override the value of ethical conduct in a research project.

1.10 Discrimination is a criminal offence and must never be applied when either hiring new research staff members or selecting participants for a human trial.

1.11 If a research institute receives a complaint regarding the conduct of one of their staff members, it must be investigated immediately. To promote an environment whereby people are not afraid to highlight instances of wrongdoing, the identity of the complainant must be kept confidential.

1.12 Research teams and the organisations they work for are culpable for the outcomes of all projects they undertake.

2 *Plagiarism and conflicts of interest*

2.1 Plagiarism is a severe breach of the ethical code of conduct and refers to utilising the work of another researcher without reference. Plagiarism is also the act of infringement upon intellectual property legislation. All quoted material must be referenced in full and, if applicable, permission should be sought before it is used in a new study.

2.2 Citing one's previously published work in a new research project is often necessary. However, all previous work must be fully referenced; failing to cite one's own work can lead to serious confusion and the author may be accused of duplicate publication.

2.3 A conflict of interest refers to any outside factor that may have an unfair influence upon the objectivity of a research project's conclusion. This can include influence from financial contributors, a researcher's desire for professional development at any cost, as well as a researcher's personal ties to the study. Conflicts of interest are often difficult to identify, so any possibility, however slight, must be reported in order to determine its validity.

2.4 Objectivity must be declared in writing at the start of a new study. If, at any point, a researcher becomes aware of either a personal conflict or one regarding a colleague, they must report to the principal investigator at once.

2.5 Authorship and credit for work undertaken should be attributed fairly and justly; taking recognition for the work of another is an act of plagiarism and will be punished accordingly. Both ghost and gift authorship must be discouraged in all fields of research.

2.6 Instances or agreements whereby funding agents can censor or edit the conclusions of a research project must never be entered; this is a clear conflict of interest and undermines the core principle of research integrity.

2.7 All funding agreements must first ascertain the logistics of how the data will be used after the project is completed, as well as who owns the rights to intellectual copyright. Researchers must aim to remain objective and individual when such negotiations are taking place.

2.8 Intellectual property is generally covered by patent, trademark, or copyright, and is therefore legally protected from anyone using it under their own name without due reference.

3 *Honesty, misrepresentation, and ethical data management*

3.1 Research staff must be honest about their qualifications and experience. Research institutes have the responsibility of vetting and checking potential candidates; if this cannot be performed in-house then private organisations can be hired to perform full background checks.

3.2 Research institutes who perform trials involving human participants must be completely honest about the risk and aims of the study when briefing the potential participants.

3.3 Researchers are to be accurately accredited for their contributions; misrepresentation of authorship is a serious breach to the ethical code of conduct.

3.4 All data should be stored in a secure manner, whether on a computer system or in hard copy.

3.5 Data should be kept for the appropriate amount of time according to criteria outlined by the governing body of the specific research field.

3.6 In order to ensure ethical data collection and management, all research institutes should have in-house monitoring systems to keep a check on the behaviour of their research staff.

3.7 It is acceptable practice for the researcher and the institution they work for to have a copy of the completed research findings. This way the intellectual property of the researcher is protected and the institution have a clear record of work performed on their behalf.

3.8 Publications must be an accurate and honest interpretation of the research project findings.

4 *Rights of the participant*

4.1 Research organisations have a duty to acquire informed consent forms from all human participants in a trial. In some areas, it is in fact a legal requirement. Participants must be fully briefed about the study, with full information pertaining to any possible risks and benefits. Informed consent is essentially required when information is sourced that would normally be kept confidential, or when the research team introduce chemical or biological agents into the participants body that would not naturally be present.

4.2 The information provided to a participant should be objective, legible, and comprehensive. The participant must receive a reasonable amount of time in which to make their decision. Any questions they may have should be answered in full, and they should be informed about how the collected data will be utilised after the project is completed.

4.3 Human participants in a research trial can pull out at any time during the course of a trial with no discredit; they must never be pressurised into continuing for the expedience of the trial.

4.4 Research projects involving animals should be designed to minimise the pain and suffering the animal may experience. If the animal is in severe pain which cannot be rectified, then immediate euthanasia is the ethical option to alleviate the animal's suffering.

4.5 If the potential participant lacks the capacity to consent on their own behalf (child or adult with mental health problems, then the consent form may have to be signed by a parent, guardian or carer. Also, if a third party is thought to be affected by an individual's participation in a trial, then informed consent may also be required. If there is any doubt, then expert help will be required.

4.6 Remuneration must never be proffered as an incentive; fiscal motivations can undermine the objectivity of a participant's decision to partake.

5 *Confidentiality*

5.1 All data protection laws and privacy-related guidelines of the institution running the project must be adhered to.

5.2 Researchers must aim to keep all private data confidential; this includes destroying any material that could prove to be a potential security breach.

5.3 All members of the research team need to sign confidentiality agreements prior to the commencement of a project. These should clearly outline their expected modes of behaviour.

5.4 Most data, particularly that involving human participants, will need to be coded before being released to the public. If coding is untenable to perform in-house, then third-party organisations or individuals can be brought into the team to undertake the necessary work. Both must be bound by confidentiality agreements.

5.5 Only when it is legal and absolutely necessary should participants be identified for their role in a human research trial. There are many nuances and laws to consider in such a case, and it is advisable to acquire expert help if in any doubt.

6 *Research proposals and planning*

6.1 When applying for grants and funding, research teams must be completely honest with the information they submit in the proposal.

6.2 Trying to make a proposition look superior through manipulated or embellished data is forbidden.

6.3 The proposal guidelines of the funding institute must be followed in full.

6.4 If the proposal is to be peer-reviewed, then the reviewer must be honest in their pre-existing relationship with the research team applying for the grant. As far as is possible, the peer-reviewer must aim to be objective and unbiased in their role.

6.5 A clear funding strategy must be outlined in the proposal, highlighting how the requested funds will be utilised. When the project is operational, the funds must be distributed as outlined in the proposal.

7 *Dissemination*

7.1 Dissemination is normally accomplished through publication, but can also be performed through conferences and workshops.

7.2 A dissemination strategy must be ascertained in the planning phase. This strategy must outline when and how the information of the study will be disseminated, in addition to whom it will be targeted.

7.3 Any person or stakeholder who is deemed to benefit from the study must be provided with access to the research project conclusions e.g. a mass mail-out either electronically or in hard copy.

7.4 The disseminated results must be an accurate portrayal of the research project.

Contributors

- Colin Hopper
- Waseem Jerjes
- Hiang Boon Tan
- Ramin Carbiner
- Zaed Z R Hamady

Declaration

The Publication Integrity & Ethics and the contributors to these guidelines acknowledge that many institutes and universities around the world have their own guidelines that deal with research ethics. These establishments expect their researchers to follow their guidelines and comply with them. The Publication Integrity & Ethics confirms that its guidelines on research ethics should not replace any existing guidelines of any establishment nor be followed by any of its researchers. However, P.I.E. is happy for any institute or university in the world, with existing guidelines on research ethics, to adapt part or all of the P.I.E. guidelines if the head of that establishment decides to do so and proper acknowledgement of P.I.E. is given.

The Publication Integrity & Ethics recognise that many institutes and universities in the developing world lacks guidelines on research ethics. P.I.E. is happy for any institute or university, who lack these guidelines, to construct their own guidelines based on this document as long as the head of that institute or university approves this decision and proper acknowledgement of P.I.E. is given.

Please note that you may require contacting the Medical, Dental or Pharmacy Council or the Department of Health in your country to seek approval before using these ethics research guidelines.

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