Publication Integrity and Ethics

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P.I.E. Guidelines: Ethical boundaries in human research

Practice Guidelines

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

Version 1 *1st Dec 2013*

Introduction

Ethical conduct during research is constantly evolving and subject to scientific, historical, and ideological factors. As these factors change, refine, and advance in the future, a robust metric of ethical conduct must be consistently referenced and adhered to. This will help ensure that no human right is infringed upon, whilst all research is undertaken for the benefit of humanity. This stipulation is known as the ethical concept of beneficence, and has developed throughout years of clinical and scientific investigation.

The Nuremburg Code was initiated in 1949 as a response to the crimes committed by German doctors in the concentration camps of World War II. The Code introduced the need for informed consent and voluntary involvement of human test subjects. As a result, any human research trials require the participant to be proffered the choice of involvement in the study. They must be fully informed to make that choice, and furthermore free to leave at any point during the trial. These principles are more commonly referred to as the ethical concept of respect. All researchers are accountable for maintaining an ethical, respectful, and open research domain, reporting any practice which flagrantly infringes upon this principle.

The ethical concept of justice entails that no singular group of the population is unfairly targeted in a study that may benefit humanity as a whole.

The National Research Act (1974) - following on from the Declaration of Helsinki (1964) - was a key development to the justice concept and resulted from the Tuskegee Syphilis Study. The study sampled six hundred African-American men that were monitored over a forty-year period but, despite the drugs being available, were never treated for their illness.

The principles of justice, beneficence, and respect are intertwining ethical barometers that define the way human research is performed. In order to make an informed judgement, any professional engaged in human research must adopt behaviour that supports them in contextualising the sometimes complex boundaries governing their actions.

Outlined below are the P.I.E. guidelines on research involving human subjects, which aim to provide a clear and lucid set of stipulations to promote ethical research activity. Only by fostering strict and just rules can the research community meet their remit of carrying out research where the expected benefits far outweigh the potential negatives to the trial participant(s). The P.I.E. encourages all research staff not only to read the guidelines, but to actively engage both in following them and recommending others to follow suit. Scientific understanding is blossoming exponentially; ground-breaking studies are taking us to the very core of human biology. Therefore researchers must be responsible and answerable to all ethical concerns surrounding their research methods in the approaching years.

Ethical boundaries in human research

1 *Informed consent of the individual*
The Oxford Dictionary definition of the term 'informed consent': permission granted in full knowledge of the possible consequences, typically that which is given for treatment by a patient to a doctor, with knowledge of the possible risks and benefits.

1.1 Before consent forms are sought or any trials commissioned, the research team needs to make a judgement about how their research will affect participants and outline any expected benefits/risks the trial may have.

1.2 As far as is possible, research should only be performed for the benefit of the test subject. All measures need to be justified with a full risk assessment.

1.3 Informed consent forms must be sought from all human test subjects before the commencement of any human research trial that sources either private information or data through intrusion or interaction.

1.4 Consent forms need to be written in plain and neutral language, clearly relaying the aims of the research project along with the potential risks, benefits, rights of the individual, and an invitation for any questions with relevant contact details.

1.5 Informed consent in behavioural sciences is required if the research team source any information that, if disclosed, may incur financial, legal, or societal implications upon the individual(s) involved.

1.6 Informed consent is necessary whereby the test subjects are from a vulnerable minority or population.

1.7 Informed consent forms should not be signed by people divulging highly sensitive data relating to or describing illegal activity that may place them in harm as a result.

In this case, alternative means must be found by the research institution whereby the voluntary nature of the sourced information is clearly stipulated, along with full disclosure of the aims, benefits, practices, methods, and procedures of the research project.

1.8 Informed consent is not required for any information that the test subject would not normally have any control over regarding privacy e.g. the behaviour of undisclosed public figures.

1.9 Informed consent is an ongoing process that needs to be checked throughout the course of a human trial.

1.10 If third parties are directly implicated in the care of a particular participant, be it health care professionals, spouses, guardians, or otherwise, assent forms may need to be acquired from them. This includes third parties that are providing specific medical treatment.

1.11 Legal guardians may be needed to provide consent in instances whereby the participant is not capable of comprehending the consequences of their decision e.g. individuals with dementia.

1.12 With regard to children, confirmation and consent from both the child and the parents or guardians should be sought. The researcher must use their own discretion when considering individuals over the age of eighteen, quantifying the type of research and the circumstances of the person in question.

1.13 In cases where the test subject is a pregnant woman, the study should benefit both mother and child. Furthermore, parental assent from the biological father is required. A circumstance where this stipulation is void is when the father cannot be reached or the child is the result of rape.

1.14 Research institutions should have a readily available publication outlining the expected code of conduct for their research staff. Clear instructions must also be made available to staff for the reporting of any behaviour which infringes upon these rules, along with the contact details of the relevant official.

2 *Confidentiality*

2.1 All research projects must comply with both current Data Protection legislations in their country as well as the code of conduct of the institution sponsoring the project.

2.2 Human research subjects must be fully aware of how collected data will be utilised after the trial is complete. This must include what the data will be, how it will be collected, who will have access to it, how it will be stored, and how, or if, it will be used for further research. In the event of further research, the participant must first sign Consent to Process form.

2.3 All recorded data must be kept secure and never divulged to any third party without prior consent.

2.4 Robust security systems must be in place to protect any information contained within computer systems and/or hard copy from hacking or theft.

2.5 Confidentiality forms need to be signed by all research staff with access to the collected data.

2.6 The identity of research subjects should remain private; all reference in the data should be signified in code.

2.7 Research data is confidential and should never be disclosed to the public.

3 *Coercion*

The primary focus of a human trial in its formative stages must be considered from the perspective of the participant and their motivations for entering the study. Within this consideration, the potential risks must also be factored. All researchers are advised to remain pragmatic, base their decisions upon pre-determined procedure, and circumvent any coercive agent from having an unfair influence on the participant.

3.1 Under no circumstance should an individual be coerced, pressurised, or proffered unreliable evidence that could in any way affect the basis of their decision.

3.2 Remuneration for partaking in a human trial must never be promoted or viewed as an incentive or as an overriding benefit to the participant.

3.3 Any payment made as compensation for travel is merely provided, and therefore must not be proffered as an incentive, reward, or bonus.

3.4 The participant must always be free to leave the trial at any point. Therefore creating fiscal incentives or stipulations that trap the participant into completing the trial must never be presented.

3.5 Ascertaining any coercive agents when dealing with potentially vulnerable individuals is of paramount importance; as there is no set definition and cases vary, the researcher must found their research proposal on pre-set guidelines and procedure.

3.6 People with disabilities, familial ties to the subject matter (e.g. the parent of a cancer victim), or are suspected to be incentivised by remuneration or other benefits, should be scrutinised to see whether their circumstances affect the righteous consent of their decision to participate.

4 *Transparency*

4.1 Research staff and institutes should promote an environment of transparency between themselves and the participants.

4.2 Any dishonesty between the research team and the human test subject must be circumvented unless deemed entirely necessary. Such instances must be backed up with a report outlining the reasoning behind the dishonesty.

4.3 The human participant must be informed about any calculated deceit in a full debrief after the completion of the trial.

4.4 Deception must never be adopted for the expedience of a researchers discourse; such an action will immediately undermine the research project as a whole.

4.5 When the conclusions of the study are published and released to the general public, they must relay all findings with accuracy.

4.6 Upon completion of the study, the findings should be forwarded to the relevant persons involved in the project including research staff and applicable stakeholders.

5 *Risk assessment and review*

The most significant challenge to any researcher in human trials is determining the potential risk to the participant. How vulnerable the participant is, how intensive the intrusion will be, and how sensitive the subject matter is, are all factors that need to be quantified before a study is submitted for review. A high risk study is one which involves vulnerable participants in a highly sensitive and intrusive subject area, and must therefore be fully justified before commencement of the trial. However a one-size-fits-all approach is limiting and severely misleading; cases must be scrutinised on their individual merit. Calculating the potential risk is vital to form a sound judgement about the moral implications of the research. The guidelines below are by no means definitive, and are more to direct the thought process when clarifying this often tricky decision.

5.1 When determining the potential risk category of participants, researchers are duty bound to utilise their discretion in a case-by-case manner. The research team are fully culpable for selecting appropriate subjects.

5.2 High risk participants who may be vulnerable to coercion include but are not limited to: prisoners; people in care homes; members of the armed forces; the elderly; and known associates of the research team.

5.3 An immediate question mark of vulnerability must be signalled if the test population will include: those under the age of eighteen, people with underlying mental conditions, people with cultural differences and foreign nationals who may have difficulty understanding the logistics and potential effects of the trial through language difficulties.

5.4 Highly sensitive topics for research can include: sexuality, abuse, race, and political views among others. Again, personal pragmatism and discretion on behalf of the researcher is needed to accurately determine the sensitivity level of the study topic.

5.5 When the human trial includes people that have been deemed vulnerable, it is the duty of the research team to heighten their focus upon any potential risk. Unforeseen challenges are a prominent part of human trial research, so preparing ahead will significantly reduce the potential of challenges once the trial has commenced.

5.6 If a test trial is required to source participants solely from a vulnerable minority, then full justification is required. This is often found in studies focusing on genetic illnesses common to a specific ethnicity or the study is gender orientated e.g. ovarian cancer.

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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.