THE IMPORTANCE OF RESEARCH ETHICS IN THE FIELD OF HEALTH SCIENCE

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Background

All humans throughout their life cycle will indisputably deal with a considerable number of problems encompassing all life aspects from social, cultural, economic, politic, educational, health, and others, and touching upon both a micro and a macro scale of all facets of life. These all-inclusive aspects of life have every so often affected one another as well. To illustrate, policies set by government in the political sector can impinge on the economic climate and public health. Simply put, a political decision from the government can determine the rise and fall of the price of basic needs of the society. For the lower and working class cohorts, such a government's decision will have a serious repercussion for the fulfilment of their daily needs. In this case, if their daily needs are gone bad, then their other needs will as well be disrupted, including problems in the fulfilment of healthy and nutritious sustenance, which in turn may serve to further prompting health issues.

The globalization era and the mobilization of residents from outside the town, outside Java Island, even overseas, and vice versa will, however, happen to initiate easy access to the transfer of various diseases and anomalies. Additionally, adverse weather conditions as a consequence of global warming and rapid development of technology that leads to great changes in daily lifestyles add to the records of the increase in health issues. More crudely however, whilst mitigation towards the infectious diseases has not fully been reached, problem on the spread of non-communicable diseases has currently been occurred at the same time, posing daunting challenges for both the society and the government itself.

Health Research

Health research is particularly undertaken so as to address and solve problems within the health field with various impacts, as has previously been illustrated. Health research by itself has two prime goals. The first target has been to surmount the problems of individuals experiencing health issues. The second objective, by contrast, has been oriented to the healthy collectives or communities where they are well advised to have been able to maintain their conditions in good health. Broadly speaking, the scope of study in the health science area is inseparable from the attempts of problem solving in the domains of prevention and promotion as well as cure and rehabilitation.

The objective of health research has been a reference in conducting studies on health field. Such purpose pertains to the type of studies proposed and the scope of the health research. Research upon which its types of conducting are based can be broken down into a dual group of traditions, namely quantitative and qualitative. The quantitative inquiry lays greater emphasis on the results in numerical format, making use of statistical tests as its analysis. The qualitative inquiry, on the other hand, is characterized by the research findings that are not generated through statistical procedure, as it seeks to delve into the reasons, providing a subtle answer to the "Why" enquiry of a research.

In the case of the scope within the health research, its scope, as previously stated, commonly falls into preventive and promotive as well as curative and rehabilitative. Research within the domain of health is particularly valuable for human life and well-being. This is because the health research provides through information about the exposure or causal factors brought about by a certain disease, factors preventing occurrences of a particular disease, and any short of doings that may overcome or treat a disease. Human in a state of good health can do various activities that are very beneficial for themselves, their families, and their surroundings, such as working, going to school (learning), doing community service, praying, and so forth. Conversely, when one is sick, then a problem within the household or an organization of the person does exist, given that the person (s/he) cannot do regular activities as usual. The person can only become a burden to his/her family or others. Besides, it can also trigger financial problems in that there are costs that are needed to cover healthcare.

Generally, research in health science is of great significance for the following reasons: can be made use to delineate the health status of individuals, groups and communities; can provide a description of the potential resources, including human resources and other resources in terms of supporting health development; can be utilised to address health issues and to provide alternative solutions concerning causes of health issues or other problems which arise within the health care system; can be applied to conduct a follow-up in the form of decision making or health development policies; can provide a lucid description both quantity and quality of the current state of health service in terms of finance, infrastructure and personnel.

Health Research Ethics

Ethics is a moral rule applying to a certain group of people (community). The word ethics has always been paired with a predicate that reflects the community. Medical ethics, which refers to the morality of doctors, is a case in point. As such, the ethics of health research is the morality norm of the research community within the health domain. Health research ethics anchors to two pillars of ethics, namely academic ethics and bioethics. The academic ethical dimension focuses upon two launch pads: 1) the integrity of researchers as scientists in maintaining and utilizing the universe, 2) the sacrifice and safety of the subject, as well as maintaining and valuing life and humanity. Meanwhile, bioethics refers to the study of ethical, social, legal, and other issues that arise within health services and Biological Sciences.

In carrying out all research activities, researchers should follow a scientific attitude and apply principles contained in the research ethics itself. Note that not all studies have risk that can injure or harm research subjects. Yet, researchers are still responsible for considering the morality and humanity aspects of research subjects

1. Research ethics in humans

All kinds of research involving humans as research subjects must apply four (4) basic principles of research ethics, as stated below:

a. Respect for Person.

There are several points that need to be taken into account with respect to this first aspect. These points are as follows: researchers should consider the possible dangers and mistreatment of research deeply. For research subjects who are vulnerable to research hazards inherent in the research conducted, protection is then needed.

b. Beneficence

In research, it is hoped that the research will have yielded fruitful results and can reduce losses or risks for the research subjects. For these reasons, the research design should fully consider the safety and health of the research subject.

c. Non Maleficence

As has previously been explained, in the research that involves human, the research should protect the research subjects from any harm or risk. It is of utmost vital for researchers to predict the probabilities of what will happen in research in order to prevent risks that are harmful to research subjects.

d. Justice

The underlying meaning of justice, in this case, is not to distinguish the subject. Yet, it is worth noting that research is balanced between benefits and risks. The risks faced are in relation to the notion of health, including physical, mental, and social.

Informed consent (herein IC) is a process whereby a research subject voluntarily grants or expresses his/her willingness to participate in the research after being informed or explained the overall scope, benefits, and risks of the research. Just after the research subject understood the given explanation, then consent was done by documenting the signature or thumbprint of the subject as evidence of agreement.

As stipulated in the Decree of the Minister of Health 1333/2002, IC is the responsibility of the researcher. The primary objectives of the IC itself are (1) to ensure that research will be conducted ethically, (2) to protect the rights of research subjects considering that the data provided is subject to confidentiality (privacy), and (3) the process of communication and education between researchers and research subjects. There at least are eight key elements in the IC. These elements are detailed in the following points:

a. Research description

The research description in IC covers a succinct description of the research background, objectives, and targets. Descriptions of research are of concern to be outlined on the IC with the aim to provide brief information to prospective research subjects.

b. Risk and inconvenience

Risk in research is the possibility of bad things arising throughout the study that may lead to discomfort to the research subject. It has been mentioned previously that research ethics applies the principle by which to minimize the risks, but these risks should as yet be explained in the IC.

c. Potential benefits.

The benefits of research, as has already been expounded, ought to be balanced against the risks.

d. Alternative procedures and treatments

If the risk has been gently estimated, the researcher should have as well prepared alternative procedures and treatment in case of the risk occur.

e. Confidentiality

The information provided by the subject is confidentiality that should be maintained and protected by the researcher.

f. Compensation

Compensation is reciprocity catered by researchers to research subjects since they have participated in research. The feedback given should be adjusted to the risks that may occur in the study throughout. Some investigators provide compensation in the form of souvenirs, money, or just a salutation.

g. Contact

The contact on the IC explains the name of the person in charge of the research along with a contact person who can be contacted (usually a telephone number). Contact is required when the subject requires confirmation regarding the study.

h. Volunteer subjects

Voluntary participation should be well described in the IC with a statement that there is no coercion or encouragement from any party to participate in the research.

Speaking of the research where humans are happened to be involved as the research subject, the following are some requirements that should be considered by the researcher:

1. Comply with recognized scientific principles, based upon adequate literature studies, whether on the basis of previous research on human or animal subjects basis
2. Have a clear research proposal as regards the objectives and reasons why the investigation is carried out in humans, sample selection, drug dose, side effects, risks, length of study, method, criteria for discontinuation of research, criteria for drop out
3. The plan and implementation of each experimental procedure is clearly formulated in a research protocol submitted to the Health Research Ethics Commission
4. Conducted by researchers with high quality and experience in their professional fields, or who are scientifically qualified and under the supervision of medical personnel who have clinical competence
5. Have an informed consent letter from the research subject and have an ethical recommendation from the research ethics committee
6. If legally unable to grant consent on the basis of consciousness, then such consent should be obtained from or granted by a legally valid guardian
7. Conducted on the basis of human rights and voluntarily; all participation subjects engage without any pressure, and they have the right to withdraw from the research at any time
8. The rights of subjects to protect their physical, mental, and personality integrity should be respected
9. Executed on a risk-benefit basis
10. Armed with adequate facilities to overcome risks during and after the research
11. Done responsibly
12. Research protocols should always consist of a statement of ethical considerations related to research and should state that the principles stated in the Declaration of Helsinki have complied.
13. In publishing research results, researchers ought to provide accurate report results. Reports that do not comply with the requirements and declaration of Helsinki cannot be published at all.

2. Health research ethics in society

Proactive and sustainable community engagement wherein would be partaken participants has been a way of showing respect for the community and the traditions and norms that are given. The involvement of community also contributes significantly to the success of the research conducted. In particular, community engagement is a means to ensure the relevance of the proposed research to the affected communities and their acceptance by the community. In addition, the active involvement of the community assists in ensuring the social and ethical values and results of the research submitted. Equally, community involvement is particularly important when research involves minority or marginalized groups, including those with stigmatized diseases such as HIV to address possible discrimination.

Society subsumed under the research does not merely include people living in the geographic area at which the research is conducted; but also consists of the various layers of society that possess an interest in the proposed research as well as the sub-populations from which the research participants are recruited. Stakeholders are individuals, groups, organizations, government bodies, or others who can give influence on the implementation and outcomes of a research project or who are influenced by the project implementation and outcomes. The process should be fully collaborative and transparent, involving a wide spectrum of participants, such as patient and consumer organizations, community representatives and leaders, relevant NGOs and advocacy groups, regulatory authorities, government agencies, and community advisory boards. In addition, it is of paramount importance to ensure diversity of views in the consultation process. For example, if community leaders are only men, researchers should actively include women's views as well. There may also be value in consulting individuals who have previously engaged to comparable research.

The research protocol or other documents submitted to the research ethics committee should have a description of the community involvement plan and have as well identified the resources allocated to the proposed activities. This documentation should specify what has been and will be carried out, when and by whom to ensure that the community is clearly defined and can be proactively involved during the research. Such requirement should be accomplished to ensure that the proposed research is relevant to the community and is acceptable as well. Moreover, the community should take part, where possible, in the discussions and preparation of the actual research protocols and documents.

Researchers, sponsors, health authorities, and relevant institutions should be aware that community involvement does not create undue pressure or constitute a ground for individual community members to participate. To eschew such a pressure, individual informed consent should always be sought by the research investigator. The researchers and research ethics committees must be aware of the point at which the community engagement process becomes a formative research stage which in itself entails ethical review. Instances of community engagement processes that may require ethical review include systematic data collection that can be generalized and disseminated in forums outside the community in which the process is implemented, as well as the generation of data that may pose a social risk to research participants.

The scope of research in the community comprises of: preventive medicine such as the use of vaccines, public health sector such as eradicating infectious diseases, family planning (contraceptive drugs), and phase IV clinical trials (post marketing study). The characteristics of community research are field trials, large sample sizes, more lax supervision or monitoring than clinical research, and the possibility of novel adverse effects manifesting themselves after a long period and that being difficult to correct.

Bellow presents the information about the research requirements that should be fully considered when the research conducted is on the community basis:

1. Should only be done if it has been through clinical research with satisfactory results
2. The research plan (design, method and protocol) and evaluation should be careful so that researchers can immediately realize undesirable circumstances
3. Research must be carried out by a research team consisting of clinical whizzes, epidemiologists and biostatisticians
4. The existence of medical facilities to deal with undesirable conditions
5. Protecting the possibility of misuse of research subjects
6. Evaluation should be done regularly
7. Risk-benefit considerations

3. Research ethics using animal experiments

The use of animals in a scientific investigation to envisage possible effects in human experiments for the purpose of the physiological, pathological, toxicological, preventive, diagnostic, and therapeutic research or to test a range of biologic preparations that cannot be gauged by means of physical chemical methods without a doubt, requires ethical considerations. The existing discrepancies within the legal system and the cultural background applied in all nations have resulted in differences in the approaches to the ethical implications of animal experiments across the countries. So far, experimental animals as an intact biological system cannot be replaced as yet. The use of experimental animals is only permitted when it is thought of to be compulsory, and it is allowed only with proper treatment by taking into account the ethical considerations and the quality of the research results.

Ethical requirements for scientific experiments using animals in biomedical research are as follows:

1. The research goal is quite valuably beneficial
2. The research design is organized in such a way that it is most likely to achieve its goals
3. The research goals may not be achieved if the scientific experimental animals are replaced with other subjects or employing alternative procedures
4. The benefits that will be gained are far more meaningful than the suffering experienced by experimental animals.

The basic principles of using experimental animals are set forth in the following lists:

1. The scientific experiment is conducted for the sake of the advancement of biological knowledge and the development of better ways to protect human health and well-being and require experiments on whole animal species
2. Where only feasible, computer simulation, mathematics and in vitro methods to condense the number of scientific experiment of animals can be utilized
3. Scientific experiment involving animals can solely be carried out with careful consideration, specifically when there is a strong relevance to human health and the advancement of biological knowledge

4. Experimental animal species should be precise and are as possible from the lowest phylogeny.
5. Researchers should treat animals as sentient beings
6. Researchers should have a shared assumption that procedures leading to pain in humans are also applied to a scientific experiment using animals.
7. Procedures that lead to pain should be under normal anaesthesia
8. For animals suffering from severe pain in the end of study, the disability should then be numbed without pain
9. Animals used for biomedical research should be guaranteed to have been in the excellence living conditions upon which the animal laboratory science is rested

Conclusions

Drawing from the above provided justifications, we come to the final conclusion that the development of health sciences is driven and directed by health research. Health research can be accomplished via several mechanisms, such as employing computer simulation models, biochemical research, or involving living materials, such as cell and tissue cultures, in the laboratory experiments which then need to be continuously explored under an integrated living system using experimental animals. In the end, before the research results can be made used safely and effectively for human health, suffice to say that the involvement of humans as research subjects to partake in the research voluntarily is truly crucial for the research. Humans who are willing to participate in the research as the volunteers may have experienced possible risk inherent in the research. Bearing this in mind, as ethical researchers, not only do the researchers value a huge appreciation for the willingness and agreement of subject volunteers, but they also should appreciate and protect the life, healthy, privacy, and dignity of the human subjects. The experimental investigations using animals should have as well been properly handled in a scientific civilized manner for the sake of militating against any harm for the animals themselves. Such moral duties have been thought of as a kernel of the reach ethics in the health science.

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