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ETHICAL ASPECTS OF MEDICAL RESEARCH IN HUMAN AND ANIMALS

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ABSTRACT:
Ethics in research is a set of principles and values that must underline all aspects of the research process of human and animal experimentation. For ethical use of animals in science "THE 3 RS "- Replace ,Reduce,Refine have been used for guiding researchers and reviewers , and are explicit in legislation governing animal use. Adequate training is an important aspect of the refinement of animal and human experimentation. The research involving the participation of human beings implicates a variety of ethical concerns pertaining to such values as dignity, bodily, integrity, autonomy and privacy. Our responsibility as researchers, scientists and carers to ensure the utmost ethical standard in all aspects of research in animals and humans. A Systematic search strategy was employed using keywords to search the literature in online databases.Our responsibility as researchers, scientists and carers to ensure the utmost ethical standard in all aspects of research involving human and animal subjects. There is also speciesism when we justify animal research since it advances human medicine. Non human subjects to highlight the importance of ethics. The argument core animal testing often surround the benefits derived from the experiments.

INTRODUCTION

Ethics in research is a set of principles and values that must underline all aspects of the research process of human and animal experimentations(Harper,

Herbstand Kalfa, 2018). The ethical standards of human experiments is about after the Nurembergtribunal passed judgment on Nazi war cromes, which included atrocious human subject experiments(Cook, Dickens and Fathalla, 2003). People enjoy a better quality of life because of these advances, and subsequent development of new medicines and treatments made possible by animal research, including both animal – right extremists and anti vivisectionist groups believe that animal experimentation is cruel and unnecessary regardless of its purpose or benefit(Festing and Wilkinson, 2007)(Anitha and Ashwini, 2017). Animal studies are needed for better understanding of physiological processes and testing of new treatment modalities aimed at better health in humans. There are many ethical, scientific, legal and economic reasons for creating sure that animals are taken care of properly and utilized in minimum numbers.(Ashwini, Ezhilarasan and Anitha, 2017) For moral use of animals in science "The 3 Rs" are used for guiding researchers and reviewers and in several countries, are expressed in legislation governing animal use. Ethical analysis to increase awareness of animal welfare issues(Russell and Burch, 1979). There have been four major UK independent inquiries into the use of animals in biomedical research: The House of Lords(2002); the Animal Procedures committee(2003); the Nuffield Council on Bioethics(2005) and the weatherall committee(2006), which specifically examined the use of non– human primates in scientific and medical research(Arnason, 2018). Adequate training is an important aspect of the refinement of animal research, and should continually be reviewed and improved(Sechzer, 1981)(Lakshmi *et al.*, 2015). Adequate training is an important thing, which should be an improved justification for acting otherwise, animals should be maintained under anaesthesia until the procedure is ended(Ghasemi and Dehpour, 2009). Responsibilities for the condition under which animals are kept, both within and out of doors of the context of active experimentation or teaching, rests with the researcher under the supervision of the animal care committee and with individuals appointed by the institution to oversee animal care(Phaosavasdi, Taneepanichskul, *et al.*, 2005). The essential components of an ethical consent for a pediatric study include that: the parents or caretakers have free choice and there is no coercion (the parents or caretakers do not feel pressured by their child physician), the description of research activities is complete and understandable and assent permission is obtained from the child whenever possible(Sharma *et al.*, 2019). These two final points are crucial in making sure parents understand consent information means taking into account the level of literacy, that parents may not distinguish between the research and routine treatment(Leibson and Koren, 2015)(Ezhilarasan*et al.*, 2017). The licensing of animal experiments normally requires an ethical evaluation process, often –times undertaken by ethics committees(Weatherall, 2007). Since considering ethics in animal experiments is a crucial issue in the modern era of medical research, which could be useful for researchers to design studies on a variety of animals(Weatherall and Munn, 2007). Legislation of animal experiments in modern societies is predicated on supposition that this ethically acceptable when certain more-or-less defined formal demands and ethical principles(Kolar, 2006)(Perumalsamy*et al.*, 2018).A Systematic search strategy was employed using keywords to search the literature in medical databases like Mesh , pubmed , google search and so on

Animal Research:

There Rs(Replace,Reduce,Refine) are established principles which are enshrined in legislation for guiding researches, reviewers and assets from the child. Scientists experiment on all individuals of animals, under the supervision to exhibit instructions for experimental methods to care, maintenance and handling(Ott and Sucato, 2014).

Replacement: are the methods that avoid or replace the use of animals in research.

Reduction: are the methods that start the researchers to obtain comparable levels of information from few animals or to get more information from the same number of animals(Foëx, 2007)

Refinement: use of methods that alleviate or shorten the potential pain, suffering or distress and enhance animal welfare for the animals used(Foëx, 2007; Thompson, 2008)

The aims are to provide independent ethical advice, particularly with respect to applications for project licenses and standards of animal care and welfare to provide support to licenses regarding animal welfare and ethical issues to increase awareness of animal welfare(Nwabueze, 2016)(Mehta *et al.*, 2019).

Human Research: Ethical considerations

The research involving the participation of a person implicates a spread of ethical concerns such values as dignity, bodily integrity, autonomy and privacy(Barry, 1987). These ethical concerns are translated into a posh regulatory apparatus within the USA, containing specific legal provisions concerning such matters as participant safety, consent and confidentiality(Morreim and HaaviMorreim, 2004). A topic of particular interest for pathologists is the handling of human tissue specimens that may be used for present or stored in future research purposes(Hakimian andKorn, 2004)(Ezhilarasan, 2018). The ethical and legal ramifications of obtaining and storing tissue samples for research purposes, with special attention to the problems of consent and confidentiality(Doyle, 1987)(Ezhilarasan, Sokal and Najimi, 2018). As well as other ethical concerns are addressed by an extensive regulatory structure pertaining to human subjects research. The historical and philosophical background culminating in the present American system of governmental command and control regulation(Howe, 1999)(Gheena and Ezhilarasan, 2019).

Historical Perspectives:

The use of animals and humans in research has a lengthy history. Dissection of living animals by medical practitioners– scientists curious about physiological processes. These early vivisections purpose, however, to describe the inner workings of animals(Phaosavasdi, Thaneepanichskul, *et al.*, 2005)(Menon *et al.*, 2018). Throughout the historical period, few philosophical or moral objections were voiced regarding the use of animals in biomedical studies. This is often maybe stunning for two reasons first, anesthetics were poorly understood and barely utilized in animal vivisections. Second the medical benefits of using animals in research were at best ambiguous during this period although both considerations would appear to agree strongly against the use of animals in research, there was clear moral consensus that the practice of

animal vivisection was not unethical(Gluck, Bell and Pearson-Bish, no date)***(Rajeshkumar, Venkat Kumar, et al., 2018).***

Tissue specimens in research:

Human biological specimens have been the foundation of pathological inquiry ever since Rudoff Virchow propounded the cellular basis of disease(Karthiga, Rajeshkumar and Annadurai, 2018). The study of human tissue affords unique and increasingly sophisticated molecular and genetic insights that progressively illuminate the detailed mechanism and pathways of human diseases. Tissue specimens could even be sought specifically to be used during a current research protocol from individuals who are either undergoing non-experimental diagnostic or therapeutic intervention for a medical problem or who are currently participating during a different research protocol(Savulescu, 2002). With increasing frequency, patients or current research participants are being asked to donate bodily tissue for storage and possible use at some future date as a part of human genetic studies whose precise details are not yet knowable(Greely, 1999).

General regulatory ethical principles:

Based largely on the recommendations of the National Commission for the protection of Human subjects in Biomedical and Behavioural Research, established by the 1974 National Research act(Sade, 2002). Physical and psychological risks to subjects are reasonable in relation to anticipated benefits to those subjects and to the importance of the general knowledge that may reasonably be expected to result(Clayton, 2005). Selection of subjects is equitable (Rajeshkumar, 2016). Informed consent is going to be obtained, including at least the things being communicated to potential participants are the purpose of the research, its expected duration and therefore the nature of any interventions(Annas, 2002). Anticipated risks and benefits of participation in the research(Allen, 2004). Confidentiality provisions relating to the research of records and any compensation or treatment available for research related injuries(Rajeshkumar, Agarwal, *et al.*, 2018).

CONCLUSION

Our responsibility as researchers, scientists and carers to ensure the utmost ethical standard in all aspects of research involving human and animals subjects. There is also speciesism when we justify animal research since it advances human medicine. Non human subjects to highlight the importance of ethics. The argument core animal testing often surround the benefits derived from the experiments. Pathologists everywhere are involved in various aspects of research involving human particular jurisdiction and the ethical principles underlying the applicable local legal rules. Efforts to objectively evaluate the value of animal research for understanding and treating human disease are particularly relevant in the modern era, considering the availability of increasingly sophisticated technologies to address research questions to the use of animals.

AUTHOR CONTRIBUTIONS

Idea and study was conceptualized by LakshminarayananArivarasu, collection of the literature and drafting the manuscript was done by B. Amrithaa, revising the manuscript for publication was done by R.V.Geetha.

CONFLICT OF INTEREST

The authors declare no conflict of interest

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