



## Study of Ethical Standards in Genetic Research

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**ABSTRACT:** The genetic researches not only has increased our medical knowledge, but also has promoted health conditions and their treatments as well. They have also brought some moral issues with themselves too. So, by taking into notice that the rapid progress in genetics and vast concentrations of information on genome and our understandings about the inheritance of diseases, necessary and essential decisions have to be made for considering human values, and the dignity of the research participants. Methods: the existing study was conducted by the examination of 50 research papers on genetic disorders, which is currently available at Jahad Daneshgahi's Scientific Information center. The selected articles were examined from the aspect of five moral genetic research guide codes. Findings and conclusion: in 42 percent of studies, individuals participated in the research after receiving their consents, only 10 percent of the study included genetic counseling for individuals. 16 percent of the studies were conducted by the permission of the moral committee, while the principle of confidentiality was observed during the studies. The accomplishments gained from all of the conducted studies have been made public. It seems that, necessary instructions have to be made in order to sensitize researches and the public to respect the ethical and moral aspects of this study.

**Key words:** Medical Ethics, Genetic Research, Informed Consent, Confidentiality

### INTRODUCTION

According to the rapid progress in genetics, the emergence of new medical technologies and human genetics and also by knowing that the human genetics is associated with the potential concerns in observing moral principles, and by emphasizing the importance of performing genetic researches with the aim of improving people's general health conditions and treating incurable diseases, it is necessary to be fully aware of moral ethics which are based on human principles and the existing laws in our country for performing genetic and medical researches. As conducted genetic researches have added to our medical knowledge and have resulted in the improvement of health conditions and treatment of diseases, it has brought some particular moral issues with itself as well. Medical information is different than other information, because of having a close relationship with individuals' personal traits and characteristics, which is due to this conventional assumption, that a person's genes form and determine his/her health status and behavior characteristics. Therefore, potential risks, such as vilification and social discrimination from employers and insurance companies for the genetic research participants come to be discussed. Furthermore, the genetic information of people, provide information on their relatives, which itself discuss the complex moral issues in the field of personal independency and confidentiality (Larijani, 2004). Genetic variants could influence the

susceptibility of a person to chronic diseases. A major purpose of analysis of human genome is detecting genes that have role in genetic disorders (Freudenberg et al., 2002). These days, the great number of genetic studies on children has incited the more complex subjects on maintaining children right and getting consent as the research participants (Jantina et al., 2011).

In Forensic pathology, DNA has been used by law enforcement and courts as a tool for identifying criminals. Although, using DNA in this field for the purpose of serving justice has a high potential, but has resulted in profound legal and social challenges as well. The increased use of DNA identification and the development of DNA banking system have led to concerns about superintendence and privacy (Nelkin et al., 1999).

A new phenomenon in genetic industry is creating various DNA Banks which is to keep and store genetic information. This action could be done by the requests of individuals, society or even researches. Performing genetic researches on the other hand, is among the goals of creating DNA Bank. In these Banks, the genetic information of various people is stored for further studies. Among the benefits of this action which could be useful to anyone worldwide, include studying the origins and causes of various diseases, treatment, and other information. With the increased use of Genetic information Banks, many governments (Gregony et al., 2011). NGO's, scientists who work on different scientific fields, doctors, and

regular public have called for the establishment of international and national frameworks and guidelines. Respecting individual's autonomy and his/her human body and maintaining confidentiality, the necessity regarding any individuals' personal information, restricting the access of irresponsible people to these information, and ultimately determining the time required to store information, are among the issues which should be seriously considered, and would also be feasible by obtaining their deliberate consent, ethics committee approval, and employing an appropriate method for keeping and maintaining the information and data regarding their medical status. In 2000, the general and specialized ethic guidelines for the purpose of creating an awareness regarding the importance and necessity of its implementation were codified in our country. Following its codification, the national specialized guide which included the ethical guide for conducting genetic research was added afterwards. The regulations of this guideline include 19 items in the field of collecting, processing, using, and storing genetic and human proteomic, and biological examples for the research purpose. (mehr.tums.ac.ir) accordingly, the aim of this study is to examine the level of ethical standards observance in genetic studies.

## METHODS AND MATERIALS

This study has been conducted by using descriptive observation and through examining various articles. The statistical population of current study includes research papers on genetic disorders, which has been published as scientific-research article and is also available at Jahad Daneshgahi's Scientific Information center (Sid.ir). The contents of 50 articles were selected for the final analysis by using non-possible objective method. The specifications of the analyzed articles have been displayed at the article sources. The selected articles were examined from the five aspects of ethic guide codes of genetic studies. These codes include: 1. obtaining the participants' consents freely and consciously, and without having any

material or non-material benefits behind our purposes. 2. Performing the genetic counseling appropriately, while genetic testing. 3. Maintaining the confidentiality of the results. 4. Acquiring the permission of the ethics committee, in the case that obtaining the consent of participants freely and consciously, is not possible. 5. The accomplishments of the conducted research should be made public and accessible for all people.

In order to analyze the gathered data, frequency and descriptive statistics were used in this study.

## RESULTS

As mentioned in the methods and materials, 50 research-scientific papers were analyzed; the chart below is about the genetic subjects under study. As it can be seen from the table1, the group which was genetically studied the most was patients who were diagnosed with cancer and included, breast cancer, colorectal, bladder cancer, and prostate cancer (%32 percent total). According to the chart information, 24 percent of participants were placed in other groups section in the chart. This group included those patients who were diagnosed with diseases such as, deafness, recurrent miscarriage, pre-eclampsia, thrombotic disease, thyroid disease, Wilson, AIDS, hemophilia, MS, smoking dependency, and low HDL levels, with a study for each case. Any of the mentioned articles was evaluated according to the five moral codes mentioned earlier in methods and material section of this paper. According to the conducted analysis, in 21 cases, the first moral code was observed in 42 percent of them. The second moral code was observed in 5 cases (10 percent). The fourth moral code was observed in 8 cases (16 percent). The third and fifth moral code was observed in all articles. The results have been shown in table 2.

In the conducted study, 7 cases were performed on mentally challenged individuals, in which only in one case the legal guardian of the mentally challenged person's consent and the ethic committee's permission had acquired.

**Table 1:** The frequency and article percentage, divided by the order of the disease which was examined in our study

Genetic disease	Frequency	Percentage
Cancer	16	32
Mental retardation	7	4
Diabetes	4	8
Thalassemia	3	6
Infertility	2	4
Hepatitis	2	4
Obesity	2	4
Digestive disorders	2	4

Others	12	24
Total	50	100

**Table 2:** The published articles status from the aspect of moral codes observance

Code	Frequency	Percentage
One	21	42
Two	5	10
Three	50	100
Four	8	16
Five	50	100

## DISCUSSION

The existence of inheritance in some types of diseases is a known matter and, in fact it also involves the prognosis and treatment of these diseases as well. The human genetic information is a very important matter and has a high position due to its ability to show genetic characteristics of any individual and also could possess a major effect on families, children, generations, and in some cases, social groups. They also may include other valuable information which is not known by our current knowledge even if we were in the position of gathering information about it. Therefore, by taking into notice that the rapid progress of genetics and the vast concentration of information on genome and fortifying our knowledge over the inheritance in particular diseases, it is necessary to take decisions considering moral values and maintaining human dignity, to ultimately lead the society to physical and mental well-being of its members (Larijani, 2004). The ethics guide in genetics follows the same moral pattern in practical medicine. The genetic studies as well as other genetic studies have to obey the principles of Helsinki statement. The matter of autonomy, usefulness, the absence of any types of harm, justice, confidentiality, and the sense of responsibility are among the basic principles (Farhadi et al., 2004). The important thing is that, since the medical information in the field of research comes with the moral issues, therefore the existence of an ethics committee seems inevitable and is necessary. (Larijani, 2004). In the conducted research, only in 42 percent of the published articles the permission was given from the participants to the researchers (the first code), 16 percent of them had been conducted with the permission of the ethics committee (the fourth code), the third and fifth codes, concerning the confidentiality of participants' information and putting the gathered information at people's disposal were taken into consideration in all studies. Genetic counseling has a key role in transferring the study results, because the genetic information has a particular complexity and also there are special sensitivity regarding them. Sometimes, the study results for the person and his/her family is in the way that makes it hard to accept. At times, this issue could influence his/her further life planning (Larijani, 2004; Weindling, 2005). Therefore, the individual has to receive an explanation

about the consequences of the study before starting it. The existing subjects and the actual level of risk should be explained to the participant and necessary counseling facilities should also be in his/her disposal (Najmabadi et al., 1990). In the conducted research, only in 10 percent of the published articles genetic counseling had been done, and in 90 percent of them, the research had been performed without the genetic counseling.

In the conducted examination, 7 cases had been performed on mentally challenged patients that only in one case the permission of his/her guardian with the ethics committee permit had been obtained. Two case studies had been conducted without the mentally challenged patient's legal guardian consent, and in four cases, the study had been conducted without obtaining the mentally challenged legal guardian's consents and the ethics committees permit, which according to the ethics guide in genetic studies, in order to perform the study, the permission has to be obtained from his/her legal representative.

According to the ethics guide in genetic studies, the participants' personal opinions and feelings proportional to their age has a decisive and important role, and therefore has to be seriously considered. The benefits of revealing about his/her health condition could result from understanding genetic characteristics of each participant. But some of them may not be willing to know about his/her genetic information. Therefore, the concept of obtaining conscious permission, taking each person's willingness to participate, and Autonomy or freedom has to be considered carefully for further studies (Larijani, 2004).

By taking into account that with the growing number of genetic counseling centers in recent years, the specialized and general educations have to take place, in order to make regular people and researchers to become more sensitive to moral aspects of studies.

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