



## **Improving Trend of Adhering to Ethical Measures in Iranian Research in Human Genetics: A Survey from 2005 to 2009; and the Road Ahead**

*Seyed Hasan SAADAT<sup>1</sup>, Khodabakhsh AHMADI<sup>1</sup>, Fakhruddin FEYZI<sup>1</sup>, \*Mostafa GHANEI<sup>2</sup>*

1. Behavioral Sciences Research Center, Baqiyatallah University of Medical Sciences, Tebran, Iran
2. Chemical Injuries Research Center, Baqiyatallah University of Medical Sciences, Tebran, Iran

**\*Corresponding Author:** Email: prof.ghanei@gmail.com

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### **Abstract**

**Background:** The overwhelming rate of progress in biotechnological research especially in human genetics, as well as the high levels of power these researches provide us to intervene in human lives, brings serious concerns on the ethical problems that may rise from these research endeavors. To address this critical issue in Iran, we conducted a study issuing publishing authors of studies in human genetics from Iran, between years 2005 to 2011.

**Methods:** We contacted 116 corresponding authors of articles issuing genetics research on human subjects, asking them that whether they have gotten either informed consent from their study subjects or ethical approval from their institutional ethics committee.

**Results:** Only 13% of the authors presented both documents; 52% had not gotten any of the documents; 19% of authors felt no need for getting the mentioned documents; 13% declared that they only gotten oral consent and 3% of authors did not remember whether they have gotten any documentation or not.

**Conclusion:** The trend for informed consent taking was improving over time, from 5% in year 2006 to 24% in 2009. The result was not satisfactory but showed good trend towards improvement, recommending more serious follow up concerning ethical aspects of articles published in human genetics.

**Keywords:** Informed consent, Ethics, Genetics, Iran

### **Introduction**

The overwhelming rate of progress in biotechnological research especially on human subjects was associated with two quite different public debates: The first viewpoint focuses on the sensations of making breakthroughs in the exploration of a science that aims to discover deep secrets of life. People with this notion believe that any attempt to make progress in genetic research and knowledge results in a better understanding of the book of life which can not only be used to improve our medical experience in curing disease,

but also will empower us to improve human life through genetic intervention for optimization of a human's power to struggle with the environment and lowering its predisposition to threats and diseases. Nevertheless, there is another opinion which raises serious concerns on the prospects of having such a profound knowledge which empowers one to manipulate life. Both of these controversial views on the research on genetics are extremely serious and ignoring any of them has awesome consequences, either by losing potential

benefits from such a fundamental knowledge, or potential monstrous things that might result from uncontrolled use from genetics research.

Besides the mentioned concerns about profound biotechnological research on human subjects, there are other concerns which deserve to be addressed. In the context of genetic research, one of the obligations of ethicists is the conditions under which an author has or has not the right to disclose data of human research to the public. From this point, the research protocol has not considerable ethical problems, but disclosure of its data to the public might make serious consequences to the subject(s) of research, their family and society (1, 2). Moreover, getting informed consent from subjects of a genetic research has sometimes been neglected, and authors have not thought that they need to get informed consent for genetic research on their patients. So, this critical issue is another ethical concern that has not been well addressed, especially in the developing countries.

Islamic republic of Iran established an infrastructure for ethical issues in medical researchers in last decade. This issue draws more concern with new rapid growth of medical science in Iran. During establishment of a process close follow up and observation is more needed. This issue needs renewal of management plan by any new results from this follow up.

As a developing country but of high rate of increase in research output (3), Iran needs to develop and implement ethical measures which observe research in the context of genetics and publication of the results. However, before any attempt to develop these ethical measures, we need to evaluate our current situation, to recognize our points of weakness for addressing first. In the current study, we aimed to study the proportion of Iranian authors publishing in genetics to assess how many of them have gotten informed consent and/or ethical documentations from either the study participants or ethics committees.

## Materials & Methods

The study protocol has been summarized in Fig. 1. As the first step, a comprehensive search of the

literature was conducted to find all articles published by Iranian authors in the context of genetics through January 2005 to April 2011. Search engines used for this purpose included Pubmed and Scopus. Keywords used for the search were “human genome + Iran” and “human genetics + Iran”. Because we needed contact addresses from corresponding authors to make communications with, efforts have been made to achieve full text of the mentioned articles. Full texts have been achieved in cases the articles were open access or we were able to achieve the full text based on the study budget to purchase. In cases an individual corresponding author was correspondent in more than one article, he has received only one email directing to one of his/her articles. Then, we contacted all the authors through an email. The text for email was unique for all the correspondents, asking authors whether they have gotten informed consent from their patients. In all initial or follow up emails where authors did not reply the email, another email has been sent to them, one month later. Then, authors who have responded to the initial email were asked about how the consent has been gotten (oral, written, etc) and we asked them to provide documentation for written informed consent, if they have gotten. Moreover, we asked corresponding authors that whether they have gotten a formal document from ethics committee of their institution; and if so, we requested a copy of the document to be sent to our address by post. All the questionnaires were reviewed and modified by Deputy of Research of the Iranian Ministry of Health and Medical Education.

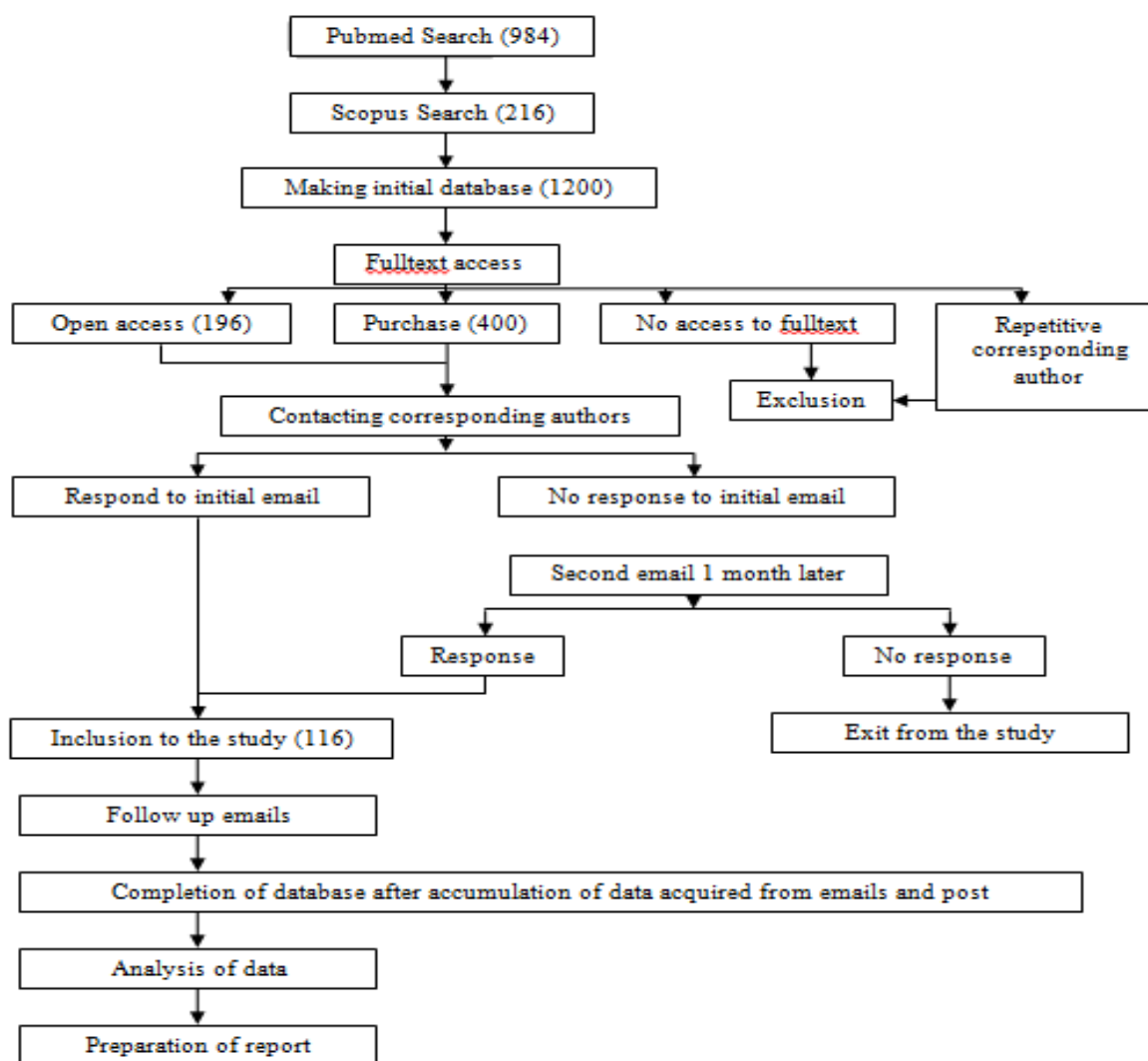
Finally, data were collected into a data base and analyzed. The study parameters in the database included study code, corresponding author, email address, consent, author’s reply, and approval by ethics committee. SPSS (SPSS corp.; Chicago; IL; USA) version 17.0 has been used for analyses.

## Results

After a search in Pubmed, 984 articles have been found to get published in the context of genetics through the specified time interval, by Iranian

authors. Two-hundred and forty one (24.5%) articles were published after Jan 2009. When the search was repeated in Scopus, the number of articles has reached to 1200. From this number, 400 (33%) articles were purchased and 192 (16%) have been gotten freely. From the 592 corresponding authors we have contacted, only 116 (19.6%) have responded to our emails, while 476 (80.4%) have not responded to either our initial or second email. From the 116 corresponding authors who have responded us, only 15 (12.9%) presented both documented approval from the ethics committee of their institution and informed consent from their study

subjects. 60 (51.7%) had not gotten either documentation from ethics committee or informed consent from patients. Another 22 (19%) authors claimed that, due to their study protocols, they did not feel a need for getting the mentioned documents. 15 (12.9%) declared that they only gotten oral consent from their authors, without any documentation from ethics committee or consent. Four (3.4%) authors did not remember whether they have gotten any documentation or not. The trend for informed consent taking was improving over time, with only 1 (5%) in year 2006 to 8 (24%) in year 2009.



**Fig.1:** Algorithm of the protocol of the study

## Discussion

This study indicates that Iranian authors need to be more firmly adhere to the ethical precautions recommended by international ethicists in the context of genetics research. Due to the improbable physical risks through a genetic screening test, several authors may underestimate the importance of taking an informed consent for this purpose; as in the current study, at least 19% of the participating authors proclaimed that they felt not they need to take it. However, we must consider that what would be revealed in counseling regarding genetic screening may disclose new information that may ultimately lead to some unwelcomed results (such as preventing an upcoming marriage or losing a job). In the setting of reproductive genetics, the issue becomes more complicated due to the social impact of a test result (e.g. thalassemia testing), although even in these case's several ethicists believe that all individuals should have the right to decide to accept or refuse having a genetic test (4). On the other hand, the true meaning of an informed consent is also controversial. The amount of information that should be given to the potential participants is an important issue. Information overload, which means giving too much data, can be harmful leading to misinformation and making the counseling process entirely misleading or meaningless (5). Moreover, future genetic research on blood samples given for some other purposes is a very delicate issue that must be more cautiously attended. Several authors may think that people will not issue that their blood samples to be used for genetic screening tests, which bring them no harm, but studies have shown that people of certain subpopulations are very meticulous about this issue and will not give consent if they are asked for (6), or they may have unwillingness due to cultural issues (7). Hidden coercion is also another crucial issue that should be seriously attended in special subpopulations (8). So, a well-understanding of social and cultural context of the society in which the genetic testing is going to be undertaken is a key issue to develop new and more perfect consent giving processes that best fit ethical orders (9,10). Before any attempt to enhance the process of taking

ethical documentation before conducting research endeavors especially in genetics; at the first step, we need to increase our education and training workshop for all faculty members and students that run these type of research besides explore the reasons behind the reluctance of Iranian authors to obtain the needed ethical documentations. Knowing these factors enables us to determine the main obstacles existing in this way, helping us to accelerate the process of implementation of ethical precaution in the context of research in human genetics. Herein, we describe some of the potential incentives one may win through bypassing formal ethical documentation processes in a research protocol.

Competition to take the limited number of faculty positions may provide a simple answer to the question: why authors may undermine ethical measures in conducting research protocols? Obtaining ethical documentations from either institutional committees or informed consent from the study subjects are time and energy consuming. The situation would become more difficult when the study is on an uncommon disorder (e.g. genetic disorders) involving a very limited number of patients, whose unwillingness to participate to the study are considered dreadful for the conduction and publication of the study. On the other hand when authors feel the study does impose no physical risk to the participants (e.g. a genetic examination), they may feel free to include the patients without acknowledging them or taking an informed consent.

Financial incentives are another incentive to conduct research projects without sufficient adherence to ethical measures. Pharmaceutical corporations and business of medicine is one of the most profiting business of all, and as any other industry needs to fight for enlarging. A good or bad aspect of the pharmacological economy is that it relies on the research on human subjects, and this makes very hard to adhere to both, the ethical precautions in research and to stay competitive in a ruthless commercial rivalry. Addressing this issue is more difficult while the faculty is not an efficient side of the relationship. On the other hand, due to the absence of a universal guideline, applicable to all corporations in the world, strict implementation of the law in one country will encourage these

corporations to do these researches in the developing countries, where there are less likely to be efficient laws to prevent ethical miss-experiences in human research. So, authors believe that to prevent unethical research on human subjects due to financial incentives, we need to put international laws which will be applied and supervised by international organizations with enough authority to prevent or punish authors or corporations performing unethical research protocols.

Maybe the most efficient way of enhancing ethics in human research issues is an effective surveillance over all research protocols perform on human subjects, including genetics research. Maybe authors refuse to respond to authors of researches like the current one, but there are international institutions which effectively survey ethical aspects of biomedical publications. In one study conducted to analyze ethical measures of biomedical journals, Resnik et al. (11), reported that only about 55% of journals had policies to prevent publications of studies having misconduct. Moreover, Neale et al. also found that several articles that publish in biomedical journals have several misconducts (12, 13). Additionally, it has been demonstrated that some authors hide their scientific misconduct by retractions and letters of apology (14); the same study has doubted that whether these apologies are sincere or only ritualistic.

In Iran, there is a law called “code of ethics”, that compels every person doing research on human subjects should take “informed consent” from the study participants, as well as ethical permission from local institutional or regional ethics committees. Researchers who do not strictly adhere to this law, including some authors studied in this survey, have violated the law and can be interrogated, and got under legal actions. One of our duties is to show authors the seriousness of legal issues as well as authorities to pursue such cases.

This study is of some limitations. For example, one may argue that the high proportion of authors who have not responded to our emails makes our findings hard to interpret. We admit that this issue brings some serious limitations to our findings; although we still believe that our findings deserve to be credited, because it would be quite logical if

we argue in return that a majority of authors who have not responded us - while the letter was approved by the Deputy of Research of the Iranian Ministry of Health & Medical Education – were more likely not to have any ethical documentation for their research. Even though, considering any of the mentioned possibilities does not change our duty towards promoting the process of getting formal ethical documentations by authors either from ethics committees or human subject who are going under genetics research.

## Conclusion

Research publications by Iranian authors in the context of human genetics are not adhered enough to the existing ethical documentations, and authors do not feel obligated to take ethical document from institutional committees and informed consent from human subjects. Ethical aspects of research in human genetics have recently received more attendance, and the process of adherence to ethical measures by researchers is going to be better. We believe that holding conferences on the relevance of research ethics, as well as authorization of ethical committees in medical institutions are the most effective of them. However, the road ahead is so long and more surveillance on implementation of law is recommended.

## Ethical considerations

Ethical issues (Including plagiarism, Informed Consent, misconduct, data fabrication and/or falsification, double publication and/or submission, redundancy, etc.) have been completely observed by the authors.

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