Chapter 13
The Informed Consent of Human Medical Research in Mainland China: A Family-Based Binary Decision Model

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13.1 Introduction

Medical research on human subjects is a necessary link in the development of biomedical technology. "Human subject means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient" (U.S. Code of Federal Regulations, title 21, part 56, sec. 102e). Medical research on humans—unlike clinical treatment—aims to test and verify unknown treatments or new drugs, and to gain new scientific knowledge. This process involves unpredictable factors and even serious risks, so the informed consent of subjects is crucial. Together with the Institutional Review Board (IRB), informed consent is considered one of "two pillars" which protect human subjects (Zhai and Qiu 2005, p. 423). The current model of informed consent in mainland China is individual-based and autonomy-oriented, which emerged in America in the 1970s. But the concept of individual and autonomous compared with the west have different meanings in mainland China. With this in mind, the aim of this paper is to find an appropriate model of informed consent. There are, of course, other measures to protect human subjects: e.g. improving the moral virtues of researchers or strengthening the IRB; I will not be concerned with those. With regard to the subjects, my essay will not concern subjects who do not have the proper ability to understand information or make a decision. Rather, my subjects are independent people who are older than 18—not teenagers or children—who are without intellectual disabilities—such as Alzheimer's disease.

The idea of informed consent originated in Western society, history, and culture; its core is personal autonomy, which is based on individualism. When this model

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was introduced in China, it was, in turn, influenced by traditional Chinese culture. Because of this influence, there are many differences between Chinese and Western ideas about the nature and practice of informed consent. In human subject research, these differences include doubt about the ability of subjects to make a decision, the motivations behind the decision, and the rights of the subject's family. Further, the process of informed consent itself is complicated. The process relies heavily on the decision-making context, such as the information provided by the researcher, the type of human subject research being carried out, the characteristics of human subjects, as well as their family status. In sum, the process of informed consent is far more complex than just signing one's name on an informed consent form (ICF). Therefore, the assumption that lets human subjects enjoy their right to informed consent unilaterally is defective in many cases. Thus, in order to protect the human subjects' interests, we must find an appropriate model of informed consent and find a way of putting it into practice. The full understand of decision-making information is the most important to an appropriate model of informed consent, but fully understand information depends on many conditions, one of them is to improve the subjects' understanding ability, family members participating the process of decision-making can improve the subjects' understanding ability, which is an appropriate model.

In mainland China there are many discussions about informed consent in clinical practice. But discussions of informed consent in human research are inadequate. So in this essay I will analyze two cases that occurred in mainland China. Firstly, the two cases will indicate that family participation in decision-making is key. Next, I will present a model of informed consent, what I call a "family-based, binary decision model." I want to argue that this model is necessary. For that purpose I will discuss the factors that influence human subjects' decision making. Further, I will make a defense of this model based on Confucian ethics. Finally, I will present some suggestions as to how to implement this model.

13.2 The Importance of Family Participation: Two Case Studies in Mainland China

13.2.1 Case A

Between 1998 and 2001, the Korea Cancer Center Hospital and the Zhejiang University Cancer Institute of China carried out a cooperative research project investigating how ginseng might help prevent colorectal cancer. They recruited more than 500 subjects from the Maqiao district in Haining City, Zhejiang Province, in China (see Wang 2006; *China Business Journal,* May 21, 2005; *Southern Metropolis Daily*, April 6, 2005). The subjects were instructed to take ginseng pills from Korea for 3 years. During the research period, some of the subjects suffered from hypertension, nosebleeds, dizziness and other adverse reactions. Some

subjects discontinued the trial, other subjects even died. For example, an old man participated in the trial and died because of brain hemorrhage in June 2000. He was then 68 years old. A woman who participated in the trial often felt dizziness after she took the pill, and her blood pressure became very unstable. Likewise, an old lady who took two ginseng pills every week for 3 years was placed in the hospital due to hypertension, dizziness and headaches. Less than 3 years after the end of the trial, she suffered from uremia and died in February 2004, being 64 years old. There were many other subjects with similar symptoms.

In this case, all subjects were from rural areas, most of them were elderly, and with little education. In fact, some couldn't even write their own names: the old lady had to press her hand print on the informed consent form. Owing to her illiteracy, she did not know the consents, functions and rights involved in the ICF at all. We know that if a subject—such as this old lady—has no reading ability or little education, we should let other people with no conflict of interest participate in the decision-making. In this case, her son noted that he wanted to know more about his mother's participation in the drug trial. But the only ICF with his mother's hand print had been taken back by the doctor or nurse before he could ask for informataion from it. We know the conventional approach is that the subject must possess a copy of the original ICF. So this case indicates that family members—such as adult children, parents, or spouses—want to participate in decision-making. But the implementation of informed consent is not standard, and family decision-making cannot be achieved if the ICF is taken back before he can discuss it with family. But this case presented further complications. Many educated children of subjects worked in other cities; some of the elderly didn't want their children to worry about them; some of the subjects misunderstood the trial as the government's attempt to show concern for the rural elderly.

13.2.2 Case B

In 1991, the governments of China and the U.S. approved a collaborative research project funded by the U.S. with research carried out in mainland China (Wang et al. 2004). The aim of the study was to investigate whether a multivitamin containing folic acid can reduce the risk of fetal neural tube defects. The trial required that female subjects take the multivitamin containing folic acid both before and after pregnancy. In order to ensure the smooth progress of this project, investigators carried out a preliminary experiment for about 1 year, from 1991 to 1992. 503 young women were selected for this preliminary experiment. All of them came from the countryside of northern China, were in their first marriage, and were never pregnant before. They had a low level of education, only half of them had the experience of going out to work, and the work was mainly agricultural. In the process of deciding whether to participate in the trial, 88% of the women's husbands, 36% of their parents-in-law, and 32% of their parents participated in the discussion. No one decision was made independently by the women's parents or parents-in-law.

Research from the preliminary experiment indicated that women do not generally seek the help of their social support system on their own initiative. But in some cases women need their husband or parents-in-laws to share the responsibility, for example when the women have been influenced by rumors, or when their decision suffers opposition of the social support system, or when some abnormal or unexpected things occur during the trial process and the women cannot explain them clearly. There are two different kinds of situations about parents or parents-in-law participating in decision-making. One situation is when parents or parents-in-law and a young couple share the very same viewpoint, or when the parents or parents-in-law are unable to participate in the decision making because of illiteracy. In this case, parents or parents-in-law tend to remain silent or understate their view, showing an attitude of non-interference or non-opposition. Another situation is when parents or parents-in-law have different perspectives, or abnormalities—such as abortion—appear during the process of taking the medicine being tested. In this case, they will tend to express their opposition. The research also indicated that the women's family members, immediate family members, intimate friends and village doctors are the most important supporters. Group psychology also plays a very important role when they choose compliance or non-compliance in the research process. Women have strong interactions with their partners who participate in the same project. By the influence of group psychology, the women are willing to make the same decision as their partners. They usually have the view that the more people participate in the research project, the smaller the risk for each person. The conclusion is that a family-based binary decision model is necessary and effective.

13.3 The Aspects of a Family-Based Binary Decision Model

Through analysis of the above two cases, I claim that a family-based binary decision model is an appropriate model for informed consent decision-making in human research in settings with a Confucian-based culture. The main aspects of this model are:

1. The person who makes a decision is binary; it includes not only the subjects, but also their families. In mainland China, "the nuclear family and stem family are still the main family structure not only in urban but also in rural" areas. (Shen et al. 2009, p. 22). Given this fact, it is common to have three generations living under one roof: parents (or a parent) live with one of their married sons or daughters and their kids. Even if in recent years the stem family appears to be declining, more and more the "temporary stem family"[1] (Yao 2012) carries the same value

[1] The three generations in a traditional stem family live together and have dinner together over a long period of time even till the older generation die. But the situation has changed with the development of the society. Subjectively, Chinese have more autonomy and hope to have more freedom. Objectively, the married children work or live in different city from their parents, so even parents

and function as the traditional stem family. Of course, other people also propose their opinions during decision making, but they are not the decision-makers. Thus, a decision-maker circle comes into being around the subject, including the subject's family members, relatives, friends, colleagues and companions who join the same research trial, etc. This circle is not an interest group, but a support group with mutual dependence and trust.

2. In this binary decision model, the interest of the subject is the first interest, and the interest of family is a secondary interest. The purpose of the family's participation in the decision-making is to consider the risks of the trial from more angles, and to propose their opinions in order to protect the interests of subject. Family interests cannot override the interests of subject. The person who makes the final decision should be the subject himself.
3. In this binary decision model, the family has a right to agree to or refuse the subject's decision to participate in research or not. That is to say, the family does not have the right to require or force a family member to participate in a trial. This is because participating in research (not for treatment) is always an issue which disturbs the normal life or the usual treatment procedures of a family member. Extra familial consent is needed in order to protect individual family members. Accordingly, for any trials, if a person decides not to participate, the family cannot require or force him/her to participate. However, for some significant trials, if a person decides to participate, he still needs to get the consent of his/her family. If the family denies consent or has different opinions, in most cases the person will not be able to participate in the trial, such as Case B.
4. The role of the family in agreeing or diagreeing with the decision of the subject will vary according to the situation of the subject. If the subject is rational, independent, and the trial has less risks, then the family's right is mainly limited to agreeing with the decision of the patient. If the trial is more important and the risks to subject or his/her family are greater, then the family has a greater right to deny the decision. Of course, the final decision should be made by the subject. The fact that the family has different rights in different situations is mainly according to Ren (仁 benevolence)—the loving of the family member.

In essence, the nature of a family-based binary decision model is a kind of transfer and share of the subject's rights. This model is supported by two kinds of considerations. Firstly, because the actual informed consent situations are imperfect, during the process of reaching a contract, subjects inevitably have various limitations.

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and their married children want to live separately. But this state is temporary—when the married children have their baby, they often have not enough time to look after a baby, so one or both the older parents live together with their children and their grandchild. Sometimes, if their economic situation is good enough, the older parents live in another house which is very close to their married children and their grandchild—that's "the distance of a bowl of soup." The distance is very appropriate: both of them have independent living space, and they can take care of each other. If the grandchild grows up, the older parents may go back to their hometown. But if the older parents are too old to live separately, they will live together with their married child again. So, living together or not can be temporary in different situation. But eventually most will live together for quite a long time, so this type of family was named"temporary stem family" by Yao Jun.

For example, subjects might be unable to make a decision because of the lack of relevant knowledge; or they might not know what to do because of being in an unfamiliar environment; or they might not know what to do because of too much information. If normal judgment is affected by the above factors, they will probably make a wrong decision. Secondly, there are ethical considerations. Imposing the responsibility of making decisions on subjects unilaterally will weaken the responsibility and obligation of doctors and investigators. If this is so, informed consent will be more and more a kind of legal formalism, and the result will harm the interests of subjects.

13.4 The Necessity of a Family-Based, Binary Decision Model

The subject can only know the written information of the consent form. And yet it is what is *not* stated in the contract that really affects the behavior of investigators and subjects, such as who are the research investors and cooperators, and what the relation among all the parties is. So in such circumstances, the subject's decision whether to participate or not is very complex. Now, family participation is highly necessary, and such participation shows a different scope and depth.

13.4.1 Problems with the Guidance of Investigators

The investigators play a leading role in the course of implementing informed consent. The information provided by them is key in helping subjects to make a decision. Incentives for investigators to enroll subjects into clinical trials are diverse and create conflicts of interest (Alpert et al. 2006). Information from investigators is always deficient due to the impact of the interests behind the project.

Firstly, there is withholding of information. The key pieces of information that affect decision making are not mentioned, such as adverse events, and whether there are other available treatment projects that can be chosen if the subject does not want to participate in the trial. In fact, the things mentioned above have detailed rules in research plan, adverse events will be noticed to IRB within 24 hours, the available treatment projects written in the research plan, but those information is not told to the subjects in detail in order to save time or recruit subjects quickly, which is different from the way in America and other western countries. Secondly, investigators can avoid important points and dwell on trivial ones. They can understate the risks and injuries that may occur during the trial, and emphasize the potential benefits of the trial. Thirdly, investigators may talk vaguely. The investigator may not be very clear about the risk assessment and the treatment after injury. Finally, investigators may oversimplify matters. The presentation of trial procedures, trial methods and risks can be excessively brief.

In this process, the investigators tend to let the subject make the decision alone for the following reasons. The first reason is the impact of the concept of self-determination. The investigators think that self-determination is an international principle and should also be obeyed in mainland China. So a subject can sign his/her name on the informed consent form by himself/herself, and need not consult with his/her family. Therefore not only in the design of the form but also in practice, there is no space for the family to participate. The second reason concerns the needs of the trial. Investigators know that allowing more people to participate in determining the participation of the subject will lower the planned speed of the research project. Further, some people originally intend to participate in the trial, but after they consult with family or friends, change their idea and abandon the trial. The potential subject loss and the necessity to recruit new subjects will extend the time of the research project. The third reason is standard practice. Unlike clinical treatment, family consent is not a necessary condition in human subject research; rather, standard practice only requires the signature of the subject. Investigators hope the decision is made by the subject himself, so this hope will have an impact on the doctor or investigator during the process of informing the patient, such as exaggerating the effectiveness of the trial products, avoiding or evading risks and injuries, and emphasizing the concept of personal autonomy to subjects. It can be seen that the lack of information and the guidance of the investigator deeply affect the rational judgment of the subject. Therefore, we propose that family or friends should participate in the informed consent process, to avoid medical paternalism in human research and to eliminate the risks raised by value guidance from investigator.

13.4.2 Family Considerations in Different Types of Human Research

In different phases and different types of human medical research, the interests of scientific research and those of the human subject conflict. Subjects will consider different factors when they make decisions, so the expectations of the family are also different.

In phase I of a clinical trial, the subjects are healthy people, the trial can't bring direct benefit to the subjects, but can have a lot of uncertain risks. In such a case the interests of the subject and those of the researchers are seriously in tension. To protect subject interest, the family's participation in decision-making is necessary in theory. But quite the contrary, in practice subjects in this phase have to make decisions by themselves. The cultural reason is filial duty. First, an important aspect of filial duty is that subjects should care for themselves and not make their parents worry. Participating in a phase I human trial may bring about risks and damages to the subject's body. This is contrary to the doctrine of the *Xiao Jing* (*The Classic of Filial Piety*), which states that "Our bodies—to every hair and bit of skin—are received by us from our parents, and we must not presume to injure or wound them. This is the beginning of filial piety." (身体发肤, 受之父母, 不敢毁伤, 孝之始也,

Sturgeon 2013b, The Scope and Meaning of the Treatise) As a member of a family, a subject undertakes the obligation of not worrying his/her family; hence, the subject might not want to consult his/her family. Secondly, Chinese culture thinks the motivations of healthy people to participate voluntarily in human subject research are questionable. Especially when the subjects are young adults or university students, their participation mostly aims to obtain high remuneration—given their usually weak economic condition. The *Xiao Jing* also states, "When we have established our character by the practice of the (filial) course, so as to make our name famous in future ages and thereby glorify our parents, this is the end of filial piety." (立身行道, 扬名于后世, 以显父母, 孝之终也, Sturgeon 2013b, The Scope and Meaning of the Treatise) So in Chinese culture, the choice of being human test-subjects is not considered honest labor, and this behavior can't be of spoken to other people. It would even bring disgrace to the family. Human subjects are aware of this, so they don't want their family to know, so that family participation during the informed consent process is missing. Of course, there are many objective reasons for why family advice could not be obtained. Because many subjects study or work in a different city than their family, and because the family's attitude to trial may be ignorance or misunderstanding, the two sides often hinder effective, accurate and timely communication about the trial. It should be noticed that even though the main family members might not be able to participate in decision making effectively, subjects can obtain some advice from other members of the family, such as those similar in age, those who are more liberal, or those with whom they have an especially intimate relationship. So at this phase, subjects prefer to make decisions together with their good friends or other subjects who participate in the same trial.

In Phase II and III clinical trials, subjects are often clinical patients, and participating in the trial can solve some medical problems or treat a disease to some extent. In these phases, the conflict between the subjects and the scientific research are reduced to a certain extent, and the relationship between them is similar to the relationship between doctor and patient in clinical treatment; the research activity is similar to clinical activity. According to a recent survey, "most patients (79.5%) are still willing to share the right of informed consent with their family in clinical treatment" (Wu and Liu 2012).It looks similar in human research. Moreover, in both phases, the recruitment and selection of subjects is non-independent. Unlike Western countries, in mainland China, a large percentage of the population with all kinds of relationships live together. Hence, recruiting subjects might involve having them introduced by relatives, friends and colleagues; doctors might seek patients to be subjects; or subjects might be assigned directly by leaders.[2] Of course, all of

[2] The 'leaders' I refer to are, in Chinese culture, ordinary people (i.e., not necessarily government officials) who are in charge of some part of an organization—for example, a school or company. Given their leadership role, people tend to trust them. For example, I have seen a head teacher (a teacher in charge of a class) of a university recruit subjects from his class during the break and encourage student leaders to recruit students actively. To give another example, a newspaper reported that since a village official allowed a new drug trial to be carried out in his village, more than a hundred people trusted him and participated in the trial. See, Li Guangming. "Dozens of Farmers in WangJiang County AnHui Province Became Subjects Inexplicably". *Legal Daily*.

them, usually with good intentions, think that providing such information and making subjects join the research process can bring them benefits. So in the two phases, not only the subject, but also the family, sees it as desirable to let their family member participate in the decision of informed consent, which can also include the subject's friends, other subjects who participate in the same trial, or other patients suffering from the same disease, and so on.

Genetics research is another special type of research, because the family's genetic characteristics, disease susceptibility, and even life expectancy could be known from subject's genetic information. The genetic information of the subject is shared with his/her family members. So when a person is making a decision whether to participate in genetics research or not, he can't decide alone, because the decision is connected with the interests of other people. Therefore, it's necessary to make a binary decision when participating in genetics research; the subject must consult with family members and make decision together with them.

13.4.3 Different Individual Characteristics of Human Subjects

The decision is made ultimately by the subject alone or after consultation with his/her family, which also relies on the subject's ability to understand, make decisions and other factors. The individual characteristics of human subjects include the following three aspects.

First, the literacy and knowledge of subjects will affect their reception and understanding of trial information. If subjects lack literacy and medical knowledge, they will not understand the trial. Carrying out informed consent effectively will be extremely difficult, and even if they agree and sign, their consent is mostly passive. In a survey, subjects who signed the very same informed consent form were asked whether the information provided is clear or sufficient. The majority of the subjects with good education answered 'no,' while the majority subjects with lower education said 'yes' (Wang et al. 2011). These results mean that the subjects with lower education do not have a good understanding of the information. They have a lower standard for the information and think that the existing information is enough. But in fact, their understanding of the trial is not sufficient.

Second, due to the long-term influence of traditional culture, subjects lack the willingness to engage in informed consent. On one hand, we have the traditional proverb that speaks of the "doctor with parental heart" (医者父母心) which makes subjects believe that doctors or researchers can make an appropriate decision that most accords with their interests as subjects. On the other hand, under the influence of traditional Chinese culture, which emphasizes family values, subjects have a higher willingness to transfer their right to consent, and their family has a higher willingness to participate in decision making (Wang et al. 2011). For instance, in

October 29, 2010, http://www.legaldaily.com.cn/index/content/2010-10/29/content_2332847.htm?node=22668 .

rural China, researchers often need to have the consent of the mayor before obtaining subjects' consent.

Third, the subjects' psychological quality could influence the implementation of informed consent. When a person is recruited to be a subject of a trial, in most cases, he has become physically weak, and maybe has been confused because of the threat of disease. Perhaps he wants to get money from the trial, or believes the research project could bring benefits to his illness or to his social status, or became a subject because he was introduced by an acquaintance, or feels embarrassed to refuse, and so on. In a word, various reasons make it so that the subject can't express his/her willingness completely when making a decision, thus they are unable to protect their own rights.

13.4.4 Influence from Family, Friends, and Peers of the Subject

Due to differences in the structure, size, economic situation, social backgrounds, and the cultural backgrounds of the family, subjects have different degrees of dependence on their family's decision. For example, for a rich family it is difficult to accept that a member of their family participate in a human trial. They all have medical insurance and have enough money to pay for the regular treatment, so the free experimental treatment with uncertain potential risks presents no attraction. On the other hand, the poor family often lacks relevant knowledge about the human trial. They usually think the trial is dangerous for their body, that it will make healthy people fall ill, and the make patient worse. So they would not agree that a member of their family should participate in human trial.

A subject's friends will also have an impact on the decision-making process. Some subjects have many friends in different lines of work and will select one or more of them to consult in the trial. This is especially true when the subject's friends engage in medical or legal work. They can provide significant advice from their professional expertise. Also, friends who are very familiar with the subject's life, values and intentions also can make important suggestions.

Moreover, subjects who participate in the same research can also play important roles in decision making. Presumably they live in the same area, the same community, attend the same hospital, the same ward, and so on. Owing to a conformist mentality, the subject will prefer to make the same decision as other subjects. If other subjects decide to participate, the subject in question will also participate. If most subjects decline, the subject in question will change his original positive idea. Of course, such decisions may not always be reasonable, but we should continue to pay attention to how other people play a role in the decision-making process.

13.5 The Ethical Defense of the Family-Based Binary Decision Model

I must emphasize that I do not want to deny the individual rights of subjects. My aim is to strengthen the subjects' capacity for decision-making, and reach a truly effective informed consent. The Nuremberg Code emphasized in its first proposition that human subjects must consent voluntarily, and human subjects must have the capacity to consent (Vollmann and Winau 1996). This means that subjects might *not* have a proper capacity to consent. Maybe they have a limited or inadequate capacity, in which case they are weak and should be protected. To address this I propose a family-based binary decision model in the decision-making process in mainland China. And this model, with its particular theoretical basis, can be defended by traditional Chinese Confucian ethics.

13.5.1 Emphasis on Family Value

From the structure of Chinese society, we know that the value of family is very important. In mainland China, everyone's identity and social role is confirmed in the family. An individual is a part of the family, so the most important decisions in one's life, such as education, health, hospitalization, employment and marriage, are all made by discussing them in the family. We believe that a person does not necessarily have the "reason, experience or capacity to make contract with others equally" (Fan 2010) when he/she is faced with deciding about a significant problem, such as whether or not to participate in a trial. When a person must make a decision whether to participate in a trial or not, because of their vulnerable status, they are not always able to make a reasonable judgment which fits their best interests. So, mutual consultation is always more proper than arbitrary decisions by oneself. In fact, too much emphasis on individual autonomy can be harmful to individuals (Fan 2011).Confucian virtue ethics asks people to make decisions based on family—as opposed to emphasizing individual decisions—so they can care for and help each other, especially about important events.

13.5.2 Emphasis on Filial Piety and Family Harmony

According to traditional Chinese culture, the family is the most basic political, economic, cultural and social life unit. The *Li Ji* (*The Classic of Rites*) taught people that the proper way of life was to first cultivate oneself in order to regulate one's family; this would, in turn, order one's states, and finally spread virtue throughout the kingdom.[3] This indicates that family harmony is a necessary stage of development

[3] The theory above is summarized from the chapter of DaXue ("The Great Learing") in *Liji* (*The Classic of Rites*). The original text is "the ancients who wished to illustrate illustrious virtue

for both personal development and national prosperity. Family harmony means the mutual obligations and responsibilities of family members.

Firstly, there are mutual obligations and responsibilities between parents and children. The *Mao Shi ZhengYi* states: "if we can be friendly to our family members, not abandon our friends, and not leave behind old friends, people will naturally be led to become more honest" (Mao and Zheng 1980, p. 410).[4] Further, Confucius affirms in the *Zhong Yong* (*The State of Equilibrium and Harmony*) that "benevolence is the characteristic element of humanity, and the great exercise of it is in loving relatives"(仁者人也, 亲亲为大。Sturgeon 2013d, p. 20). It means that the first and most important thing is to love parents. Filial piety is the most important of all virtues. Filial piety is love from the heart. Filial piety means making parents happy, comfortable; sons and daughters must not act contrary to the wishes of their parents. Filial piety also means that sons and daughters must strive to do everything to minimize their parents' concerns for them; the kindness and care is mutual. Secondly, there are mutual obligations and responsibilities between husband and wife. A harmonious marital relationship is the primary factor in family harmony. Spouses who discuss the research trial embody charity. Thirdly, there are mutual obligations and responsibilities between siblings. Brothers and sisters who live in harmony show respect to parents and elders. Hence, individuals and families are in a close relationship; the concern of one member often requires the family to make a decision. Family autonomy is often associated with personal autonomy. In human research, whether a family member participates in research is not regarded as a purely personal problem, but as a family problem. So informed consent decisions tend to have family involvement; such decisions are considered the responsibility of the family.

13.5.3 Emphasis on Friendship

The Confucian attaches great importance to friendship. According to Confucianism, friends should follow Li (礼etiquette), Ren (仁benevolence), Yi (义righteousness), Zhong (忠loyalty), Shu (恕forgiveness), and Xin (信integrity) with each other. Friendship has a special status among the five cardinal kinds of relationships because of its particularity. Its particularities are selectivity, equality, integrity and mutual encouragement (Wang 2007). The *Analects* states: "friendship with the upright, friendship with the sincere, and friendship with the man of much

throughout the kingdom, first ordered well their own states. Wishing to order well their states, they first regulated their families. Wishing to regulate their families, they first cultivated their persons". See, Sturgeon 2013c.

[4] The *Mao Shi ZhengYi*, also named *Mao Shi Xu*, is a book annotating the *ShiJing* (*The Book of Poetry*, a famous classics in Western Zhou). The authorship of Mao has not been confirmed, but it is generally thought that it is MaoHeng in the Han Dynasty. This book has no English version, so I translate the sentence myself. The Chinese text is: 亲亲以睦友, 友贤不弃, 不遗故旧, 则民德归厚矣.

observation—these are advantageous ”(Sturgeon 2013a, JiShi, p. 4). There is horizontal equality between friends—friends both fulfill obligations and share rights. Friends can help each other because the relationship is based on uprightness and is not for personal gain. So mere personal interest can be avoided. The help of a good friend can provide a more objective view and meaningful advice about for informed consent. Another particularity of friendship is integrity. *The Analects* states: “in his intercourse with his friends, his words are sincere.” (Sturgeon 2013a, XueEr, p. 7) The relationship between friends is not hierarchical. Their relationship is maintained by good faith. These features provide the possibility for the subjects to get effective help from their friends.

13.6 Some Suggestions for Implementing the Family-Based Binary Decision Model

The implementation of a family-based binary decision model needs to be supported by policy or ethics. But only a few special Chinese guidelines on clinical trial have the regulation that requires family to participate in decision-making. This is because the trials are special, such as the clinical gene trial and the clinical vaccine trial etc. For example in 1999, the policy of “The Guidelines on Application of Clinical Trials in Genes” published by China Food and Drug Administration (CFDA) stated: “The gene treatment can start only when the patient *and* family understand the information adequately and the family sign the ICF” (1999, Appendix 9; II Content of Application Material, 6 Ethics). In 2003, it was revised to state: “The gene treatment can start when the patient *and* family understand the information adequately and not only family but also patient sign the ICF”(CFDA 2003, II Content and Quality Control. 8 Ethics). Both items highlight the importance of family members during decision making. These policies display the concept of a family-based binary decision model. The practice that patients themselves and family members sign the ICF together, which respects the right of informed consent of patients while following traditional Chinese culture, might be a better solution at present. But this policy is only for the gene research, but not for other medical research. Most guidelines just need the subject’s agreement and signature. I will now present some suggestions to implement a family-based binary decision model.

Firstly, a family-based binary decision model needs to be written into the national laws and regulations, eapecially some important guidelines published by the National Health and Family Planning Commission of the People’s Republic of China or China Food and Drug Administration, such as “Ethical Guidelines for Biomedical Research Involving Human Subjects”, (NHFPC 2007) and “Guidelines of Ethical Review in Drug Clinical Trials”(CFDA 2010). I suggest that these guidelines should put forward some clear demands or provisions, such as: “in research projects involving human subjects, the investigator or doctor must provide information to the subject and his/her family, and have both sets of signatures. If they do not procure the signature of the family, investigators should explain why this research

does not need the family's advice." Accordingly, IRBs should pay more attention to trials with more or uncertain risks. If the research project is very complex, the duration of the research project is very long, or the research involves family interests, the IRB should require that both the subject and the family to sign the informed consent form.

Secondly, the current informed consent form in mainland China has no unified format, and the contents are too simple. Thus the ICF do not have enough information for subjects. Therefore, a review of the process of informed consent is more important than a review of a signature. The IRB should play a supervising function, and should make the family really participate in the decision-making process. The process could be supplemented with a survey and individual interview to inquire into the process of decision-making, and find some appropriate ways to implement a truly binary decision.

Thirdly, the IRB should serve the function of education and training, announcing the advantage and necessity of binary decision process. It should demand that subjects read the ICF with their family or friends, consult each other, and then make a decision together. Of course, the result of such requirements would increase the workload of the investigator, and even make it difficult to recruit subjects. But I believe that, in the past, the recruitment of subjects has been simple and cheap in mainland China. This is due to the subjects' inability to protect themselves and due to the lack of social support systems. It is impossible to improve the ability and autonomy of subjects in a short period, and the social support systems will not be set up quickly. Relatively speaking, family support is more readily available in all social support systems, and binary decisions are easy to implement through informed consent.

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