Effective Implementation of Informed Consent for Genetic Resource Sample Collection from Ethnic Minority Populations in China

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Abstract

China is endowed with abundant population resources and pronounced environmental heterogeneity. The diverse ethnic groups exhibit rich variability spanning physical characteristics, physiological data, genetic phenotypes, and genotypes, thereby providing exceptional resources for research on endemic diseases, familial disorders, population migration, and genetic anthropology. Prior to conducting research on human genetic resources, securing proper informed consent for sample collection in accordance with ethical principles and relevant administrative procedures is of paramount importance. However, disparities in cultural customs, educational backgrounds, and ethnic beliefs among ethnic minorities present significant challenges to obtaining informed consent for human genetic resource sample collection. This article expounds upon key considerations for signing informed consent forms when collecting genetic resource samples from populations in China's ethnic minority regions, encompassing the selection of appropriate informed consent models, procedural frameworks for ethnic minority informed consent, and the imperative for informed consent processes to fully account for the distinctive characteristics of ethnic cultures and associated taboos, thereby offering guidance for researchers.

Full Text

How to Conduct Informed Consent for Genetic Resource Sample Collection from Ethnic Minority Populations in China

1. Importance of Signing Informed Consent Forms

Informed consent is the primary task in conducting human genetic resource research in ethnic minority regions. Signing informed consent forms is required

for all scientific research involving human subjects. While scientific research aims to promote human welfare, it also encompasses the long-term interests of both researchers and donors. Research in minority areas must particularly emphasize procedural correctness. With increased protection and awareness of human genetic resources, especially in minority autonomous regions and concentrated minority areas, genetic resource collection and application require strict approval systems and documentation from relevant regional departments. Some researchers, however, fail to complete these procedures, creating obstacles for future use of these samples. A typical example of non-compliance is collecting human genetic resource samples without signing informed consent forms, which not only violates ethical principles but also renders these samples unusable for future multi-center domestic or international collaborative projects. Without proper informed consent, these valuable resources lose their application value.

Many minority areas in China have lower economic development levels, weak healthcare infrastructure, and lagging health services. Some minority populations have never even seen blood collection needles. Cultural customs and religious beliefs create significant barriers to informing donors and obtaining consent. Whether collecting blood, swab, or saliva samples, the ultimate goal is to obtain human genetic material. However, minority populations often place great trust in local governments and officials. Therefore, genetic resource collectors should first coordinate with relevant government agencies to gain their effective support and assistance. Inviting them as volunteers to help promote the research or to lead by example in donating samples can be effective strategies.

2. Scope and Procedures of Informed Consent

Informed consent primarily involves two scopes: individual consent and national consent. Individual consent requires informing research subjects about relevant information before scientific research begins, allowing them to make autonomous decisions. National consent requires obtaining permission from the sovereign state when acquiring human genetic resources across borders or conducting related scientific research. Researchers applying to use human genetic resources must obtain both administrative permission from the Human Genetic Resources Management Office and informed consent from donors. According to the Interim Measures for the Management of Human Genetic Resources by the Ministry of Science and Technology, collection and preservation of genetic resources from special populations require prior declaration and approval.

Based on our practical experience, many ethnic minorities in China have their own customs and religious beliefs, which pose challenges to signing informed consent forms. Informed consent reflects the equal relationship between researchers and donors, embodies respect for individuals, and represents recognition of research value. It is one of the core principles of ethics and the most basic requirement for protecting donor rights.

3. Ideal State of Informed Consent

Informed consent models for human genetic resource collection are generally divided into three types: specific consent, broad consent, and blanket (total) consent. Specific consent refers to consent for a particular study. Broad consent is used for medical research where future research content is uncertain, applicable to domestic or international scientific cooperation. Blanket consent means that after obtaining consent from human genetic resource providers once, no further consent is needed for any research, including all disease studies and all purposes (both commercial and scientific).

Both broad and blanket consent have two key features: First, after a single consent, no further consent is required for any research; second, commercial benefits derived from research results need not be shared with donors. For collection in China' s ethnic minority regions, collectors and researchers must consider the religious values and preferences of minority communities in advance. Donors' religious values and preferences should be incorporated into individual informed consent statements. These two consent methods can reduce the burden on donors who might otherwise be repeatedly asked for consent, and help researchers avoid spending substantial time and resources seeking re-consent that donors may not consider important.

4. Respecting Religious Beliefs and Related Taboos

Human genetic resource collection must respect ethnic religious beliefs and customs. For example, in Muslim-concentrated areas of China, besides obtaining approval from civil affairs bureaus and various government levels, researchers must effectively communicate with respected community leaders such as elderly religious figures or Imams. Only after obtaining their consent can work proceed.

Ethnic minorities have developed unique religious beliefs with relatively stable follower groups throughout their history. These beliefs are diverse and complex, forming dynamic structural balances and demonstrating the pluralistic characteristics of Chinese civilization. Minority populations are highly sensitive to whether their customs and religious beliefs are respected, often viewing this as a matter of ethnic respect. Traditional customs formed by minorities must be fully understood and respected; otherwise, serious consequences may arise.

For instance, a genetic study of the Havasupai Indians in the United States [5] collected blood samples from tribe members living in near isolation in the Grand Canyon. While the researchers conducted genetic disease studies, they also investigated tribal origins. One paper suggested the Havasupai crossed the Bering Strait from Asia to North America, contradicting tribal legends and history. Another paper reported consanguineous relationships among the Havasupai, which the tribe considered an attack. They sued Arizona State University, which spent enormous resources on the lawsuit.

Other ethnic groups, such as the Yi and Tibetan peoples, have similar situations

that differ significantly from Han Chinese practices. To respect local customs, oral consent forms may be used, though most research requires written forms signed by village heads or clan leaders. However, oral consent must involve a third party—typically a local doctor—as a witness.

5. Benefit Sharing in Minority Informed Consent

Human genetic resource samples are crucial for scientific research, which primarily advances science and technology without direct economic benefits. Consequently, ethnic minority populations in China cannot obtain financial or other benefits from donating genetic resources and data. However, flexible application of fair benefit-sharing principles in informed consent is necessary.

Genetic research requires large sample collections and substantial time investments. Donors in minority regions typically do not demand highly specialized research findings, making them unable to receive any benefits, financial or otherwise. Therefore, biobank collectors or researchers should provide appropriate compensation. Economic compensation mainly includes transportation subsidies and nutritional supplements. For example, when our research group collected samples from the Yi ethnic group, many Yi compatriots walked dozens of kilometers of mountain roads to donate. Providing appropriate transportation subsidies was reasonable. Similarly, when collecting samples from Tibetan farmers in western Sichuan, who left their farm work to participate, providing work-loss compensation was appropriate.

These costs can be included in research project budgets or covered through corporate donations. When collecting samples in Qinghai' s plateau region during freezing winter, we contacted a Shanghai enterprise to donate coal to local schools, solving students' winter heating problems and gaining local community recognition. The foundation of benefit-sharing in minority informed consent lies in trust and respect.

6. Risk Control in Minority Informed Consent

The greatest risk in collecting human genetic resource samples and information from ethnic minority populations is privacy leakage. Under current technological conditions, human genetic resource sample collectors and institutions have a responsibility to protect donor identities and take preventive measures [10]. Only researchers who can demonstrate secure data protection and confidentiality measures can obtain authorization to use human genetic resources and data.

Collectors typically use coded identifiers for samples and survey information. When using human genetic resources, researchers only receive a unified code without phone numbers or any identifying information. Research results must be published with anonymized data that cannot identify individuals. Health risk control for donors primarily involves hygiene education after blood collection to prevent infection, as well as emergency response and education for donors who

experience fainting during blood collection. Proper protocols and public education should be established to prevent work interruptions due to mishandling such situations.

7. Making Informed Consent Understandable for Minority Populations

When recruiting research subjects in minority regions, informed consent explanations should be as simple and understandable as possible. Due to cultural customs, some minority populations believe that donating blood samples causes loss of soul and serious health consequences. Others demand high economic compensation for their blood, making collection extremely difficult.

In such situations, our research group typically first obtains strong support from local governments at all levels. The government organizes minority populations and uses local dialects and colloquialisms to explain research purposes, potential risks, and benefits in accessible ways, making it easier to gain public acceptance. We also collaborate with local health institutions to provide health education and medical services. Medical services should precede donation requests, and donation must be completely voluntary.

In remote mountain villages where residents have never undergone blood tests due to cultural influences, collectors must personally demonstrate the process to serve as role models. For instance, when collecting blood samples from Tibetan students in western Sichuan during freezing winter in classrooms without heating, solving their coal supply problem first was essential for gaining cooperation.

8. Consultation Rights in Informed Consent Forms

The contact person and phone number listed on informed consent forms must be genuine and responsive, not merely symbolic. If donors have questions, they should be able to consult human genetic resource collectors. Local government officials may verify contacts on-site by calling, and some donors may inquire about research progress. However, some consultations may involve medical advice unrelated to sample collection, which should be handled appropriately.

9. Return of Research Results

Scientific research results are typically used for research purposes only and are not fed back to individuals. Only when findings reveal significant health information—such as a potentially fatal disease—should donors be notified. Therefore, collectors must avoid promising unrealistic result-return policies. A practical approach is providing donors with a medical examination report from a local hospital.

10. Ethical Review of Minority Genetic Resources

When conducting research on economically disadvantaged minority populations, rigorous scientific justification is essential to ensure that research benefits outweigh potential risks and that informed consent is truly voluntary rather than coerced. With the advancement of precision medicine and the Healthy China strategy, China' s biobanks face unprecedented development opportunities, but related ethical issues are becoming increasingly prominent [11]. How to properly conduct informed consent for genetic resource collection from minority populations is a critical issue in biobank construction.

For precious minority genetic resources, such as establishing a genetic resource bank for plateau-dwelling populations, long-term preservation should be maintained with a mechanism that balances protection and development. Perhaps a mutually restrictive sharing mechanism would be an effective approach for protecting minority genetic resources.

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Note: Figure translations are in progress. See original paper for figures.