Postprint of Standardized Design of Biobank Informed Consent Forms

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Abstract

The signing of informed consent forms constitutes the core of ethical framework development for biobanks, with its structure encompassing two principal components: "information disclosure" and "autonomous consent." Based on the characteristics of contemporary biobanks, this paper proposes a standardized design for biobank informed consent forms, specifically delineating the core contents and requirements of the two-part process from "comprehensive notification by the biobank"to "full comprehension by donors,"for the reference and guidance of biobank practitioners.

Full Text

Standardized Design of Biobank Informed Consent Forms

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Abstract

The signing of informed consent forms constitutes the core of ethical construction in biobanking. Based on the characteristics of current biobank development, this paper proposes a standardized design—an exemplary template—for biobank informed consent forms. The consent comprises two main components: the

"informed" portion and the "independent consent" portion. This paper delineates in detail both of these two parts, namely "fully informing the donors" and "complete informing of the biobank," and presents a list of related requirements, hopefully to provide a reference for biobank practitioners.

Keywords: biobank; informed consent form; standard

Biobanks involve the collection, storage, and sharing of human biological samples and associated information, presenting ethical issues in every operational aspect [1]. Informed consent represents the hallmark and critical component of biobank ethical construction, occurring before biological sample and information collection but functioning throughout the entire process from collection to utilization. Unlike conventional consent for a specific project with clearly defined research purposes and timelines, biobank consent requires donors to grant permission for future, often unspecified, types of research. Given the inherent uncertainties in biobank construction and management, this paper primarily addresses standardized content for biobank informed consent forms based on current biobank characteristics, combined with ongoing ethical requirements and challenges in biological sample collection and utilization, to serve as a reference for practitioners.

1. Biobank Responsibilities and Informed Consent

A widely recognized concept defines biobanks as comprehensive resources that standardize the collection, storage, and application of biological specimens, biomolecules, biological information, and associated phenotypic data, integrating sample information management and utilization with related clinical and research data [2]. Informed consent represents the organic integration of "informing" and "consenting," wherein the biobank comprehensively discloses to donors how biological samples and data information will be obtained, and whether samples and information will be used for collection, future scientific research, commercial development, and translation. Donors or their legal guardians must be able to autonomously decide whether to donate biological samples and provide personal information, and whether to consent to such uses, thereby making autonomous and voluntary decisions while reducing the possibility of coercion or inducement. Informed consent documents must be comprehensible to donors, guardians, or agents to facilitate reading and understanding.

2. Applicable Scope of Biobank Informed Consent Models

Informed consent models must comply with national, regional, and local laws and regulations. Based on biobank collection content and research projects, informed consent models can be broadly categorized into three types: full informed consent (also known as "blanket consent"), broad informed consent, and specific informed consent [3]. These models apply to different types of biological sample collection and preservation.

Full informed consent, or blanket consent, is applicable to donation of biological samples and data for all disease research, commercial, and other research projects, and is highly valued by biobank developers for its significance in promoting biobank construction and future scientific development. Broad informed consent applies to donation for all disease research. Specific informed consent generally applies to research projects with clear research purposes and timelines, such as disease-specific sample collection.

Considering current practical circumstances, biobanks should establish a multi-tiered informed consent and choice presentation for donors, facilitating 权衡利弊 (weighing pros and cons) and selection after careful consideration. An "opt-out" approach may better suit China' s national conditions.

3. Main Content of the Informed Consent Form

The main content of an informed consent form includes two major components [4]: first, the biobank's full disclosure to donors, and second, donors' full comprehension. This encompasses: (1) informing donors about the biobank' s research plan and collection scope; (2) informing donors about ethics committee approval status; (3) informing donors whether they will be re-contacted after sample and data collection; (4) informing donors about biobank work procedures and research status; (5) informing donors about risks and benefits of participation; and (6) informing donors about their rights and interests.

4. "Informed" Disclosure Content

4.1 Basic Biobank Information Disclosure Basic biobank information includes: the biobank' s name, organizational structure, and whether it is affiliated with an enterprise or research institution, along with relevant stakeholder information.

4.2 Research Plan and Sample Collection Disclosure 4.2.1 Research Plan Purpose and Significance Disclosure
Large or super-large demonstration biobanks should clearly describe and inform donors whether the research plan has obtained national, municipal, or other scientific project approvals, as well as the purpose and significance of relevant biological sample and data collection.

4.2.2 Biological Sample Types and Data Collection Disclosure
Donors should be informed about: which populations are suitable or unsuitable for participation; what participation entails (including research procedures, required tests, and cooperation needed); expected study duration; and whether research results will be fed back. When collecting biological samples involves genetic information or related genetic testing, the informed consent form should explicitly state whether genetic testing will be conducted, as the use and sharing of genetic data must comply with specific legal and regulatory requirements [5].

The types of biological samples and data collected should be disclosed, including: personal basic information, medical diagnosis and treatment information, and health-related information. The collection method, technical personnel involved, and collection workflow should be specified. If clinical test residual samples are to be used for other research projects, re-consenting is required. If donors do not consent, the samples cannot be used for biobank collection and research.

4.3 Ethics Approval Disclosure Donors should be informed whether the research project has obtained ethics committee approval, including the ethics review project name, number, and approval opinion.

4.4 Re-contact After Sample and Data Collection Disclosure Informing donors whether they will be re-contacted after donation is crucial. If donors do not wish to be re-contacted, they should be allowed to refuse, with corresponding options provided in the consent form for them to check.

4.5 Work Procedures and Research Status Disclosure 4.5.1 Biological Sample and Data Preservation Disclosure
Donors should be informed that biological samples and data will be securely preserved using state-of-the-art confidentiality technologies for medical research purposes.

4.5.2 Biological Sample and Data Usage Disclosure
The usage of biological samples and data should be described in detail. To maximize public benefit, samples and data may be used in broad medical research and currently unknown research fields.

4.5.3 Protective Measures for Sample and Data Access and Transfer
To protect donor privacy, protective measures for biological sample and data access and transfer should be disclosed: donor information will only be linked to names through a code identifier; only certified and authorized personnel can use this code; the biobank will employ double-coding technology to ensure information security and reduce the possibility of donor identification by unauthorized individuals; third-party access to samples and data will be double-coded protected.

4.5.4 Biological Sample and Data Retention and Disposal Methods
If the research project has a defined duration, donors should be informed about disposal methods after expected use of samples and data concludes. When samples and data are used for medical research with uncertain timelines, they may be preserved long-term or temporarily, with specific explanations provided for donor consideration. Unused samples should be returned to the biobank or destroyed.

4.6 Risk Disclosure 4.6.1 Donation-Related Health Risk Disclosure
Donors should be informed that donating residual biological samples from clin-

ical procedures or providing additional samples for medical research will not entail additional health risks.

4.6.2 Donation-Related Confidentiality Risk Disclosure

Donors should be informed about limited risks to confidentiality. The biobank management will implement all effective measures under current technical conditions to protect donor privacy. Only researchers who can demonstrate reliable data protection and confidentiality measures will be authorized to access biological samples and data.

4.7 Personal Rights Disclosure 4.7.1 Voluntary Participation Disclosure

Donors should be informed that participation is completely voluntary. They may refuse participation without affecting future healthcare or other legal rights, and may freely withdraw consent at any time without giving reasons and without fear of any detriment.

4.7.2 Withdrawal Rights and Procedures

Even after consenting to participation, donors may withdraw. The biobank management must communicate with donors about withdrawal modes, which should be implemented through protocol documentation. If donors withdraw, they should not bear costs for research-related tests or operations already performed.

4.7.3 Benefit Sharing Disclosure

The issue of benefit sharing from biological sample donation is increasingly prominent. Avoiding discussion may create future problems. Biobanks should have relatively clear judgments on whether donors will obtain economic benefits from the use of their donated samples and data—specifically, whether commercial benefits from research results will be shared with donors. It is more reasonable to inform donors that they will not receive economic benefits from potential commercial applications of research results. Biobanks are established to promote medical development, knowledge growth, and societal benefit.

4.7.4 Research Results Return Disclosure

Returning research results can be understood as a form of donor benefit. The content and format of results returned to donors should be designed into biobank protocols and informed consent text, requiring meaningful discussion with donors and ethics review committees. Biobanks should follow three principles in research result feedback: (1) results should have clinical diagnostic or therapeutic significance; (2) uncertain health information should not be provided; and (3) focus should be on abnormal test signals with reminders for further examination, not medical diagnosis.

4.8 Right to Consultation Donors should be informed that if they have any questions, they may consult relevant responsible persons, with contact information provided. They may also contact the ethics committee when necessary to

obtain opportunities for inquiry and discussion.

5. "Consent" Content of the Informed Consent Form

5.1 Donor Consent Statement Disclosure The consent statement should primarily include: (1) confirmation that the donor has carefully read research materials and obtained satisfactory explanations for any questions; (2) understanding of research materials and potential risks and benefits; (3) confirmation of adequate time for consideration; and (4) agreement to the sponsor' s use of samples and data according to disclosed content. Donors will receive a copy of the signed and dated informed consent form.

5.2 Donor Checklist of Consent Options 5.2.1 Sample and Information Collection
Donors confirm they have had sufficient time to consider and voluntarily participate.

5.2.2 Informed Consent Model Selection
For example, blanket consent or tiered consent options.

5.2.3 Consent for Sample and Data Use
Donors may consent to sample and data use for: teaching; institutional research; domestic research collaboration; international research collaboration; or commercial development such as biomarker research or new drug development.

5.2.4 Genetic Testing
Whether donors consent to genetic testing of samples.

5.2.5 Data Return
Whether donors require research data to be returned to them.

5.2.6 Limited Confidentiality of Private Information
Options regarding privacy protection measures.

5.3 Signatures 5.3.1 Donor Signature
Requires donor name, contact information, and signature.

5.3.2 Biobank Signature Requirements
Same requirements as for donor signature.

5.4 Other Provisions The informed consent form should include the biobank' s code. The biobank or researcher retains the official version, while the donor retains a copy.

6. Conclusion

The contradiction between information protection and sharing in medical research aims to both ensure full respect and protection for individual donor rights

and facilitate medical research development and innovation. All biomedical research involving human subjects must follow ethical norms, and collectors must obtain donor consent before biological sample and information collection. This protects donor legitimate rights and interests while shielding collectors from litigation [6]. The ethical norms of biobanks, particularly regarding informed consent models and content, will continue to develop and improve alongside biobank construction and development. Biobank ethical construction faces a long and arduous task.

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