本調査にご回答くださった皆様へ

おねがい

1．ご多忙とは存じますが、本調査用紙は、同封の返送用封筒をご使用の上、3月25日（月）までにご投函下さいますようお願い申し上げます。

2．本研究班では、今後さらに、倫理審査委員会についての聴き取り調査や倫理審査委員会の傍聴などを計画致しております。もし、私共のこうした計画に協力してもよいというお気持ちがございましたら、同封の葉書に必要事項をご記入の上、その旨をご連絡くださいますようお願い申し上げます。

3．今回の調査結果のまとめを希望される方も、同封の葉書でその旨をご連絡ください。

4．お差し支えないようでしたら、貴施設の倫理委員会または遺伝子解析研究の倫理的問題を審査する委員会の「倫理規定」、「設置要綱」、「運営規定」、「書類審査などに関する取り決め」（I. 1-4 でお尋ねしたこと）、「倫理委員名簿」などを資料送付用封筒に入れて厳封し、本調査用紙と共にお送りいただけないでしょうか。よろしくお願い申し上げます。

なお、資料送付用封筒は、ご返送いただいた時点で調査用紙とは分離し、お答えいただいた内容との照合は行えない状態にすることを申し添えます。

お忙しい中、調査にご協力下さいましてどうも有り難うございました。

平成 13 年度厚生科学研究費「遺伝子解析研究、再生医療等の先端分野における研究の審査および監視機関の機能と役割に関する研究」班（主任研究者　白井泰子）

調査担当　玉腰暁子（名古屋大学大学院医科学研究科）
白井泰子（国立精神・神経センター精神保健研究所）
本調査に関する問い合わせ先：主任研究者　白井泰子
〒 272-0827　市川市国府台　１－７－３
国立精神・神経センター精神保健研究所社会精神保健部
TEL: 047-372-0141(代)　FAX: 047-371-2900

資　料　2

<Appendix>

Ethical Guideline for Research on the Human Genome/Genes

March 29, 2001

Ministry of Education, Culture, Sports, Science and Technology

Ministry of Health, Labor and Welfare

Ministry of Economy, Trade and Industry

Table of Contents

Preamble

I. Basic perspectives

1. Basic policy

2. Scope of application of these guidelines

II. Responsibilities of the investigators

3. Basic responsibilities of all the investigators

4. Responsibilities of the head of research institution

5. Responsibilities of principal investigator

6. Responsibilities of personal information manager

7. Responsibilities and membership of the ethics committee

III. Basic attitude to donors

8. Informed consent

9. Disclosure of genetic information

10. Genetic counseling

IV. Handling of samples

11. Use of stored samples for clinical purposes

12. Storage and disposal of samples

V. Revise

13. Revise

VI. Glossary

14. Glossary

(1) Samples

(2) Health care information

(3) Research on the human genome/genes

(4) Genetic information

(5) Personal information

(6) Anonymity

(7) Personal information manager

(8) Informed consent

(9) Proxy consent

(10) Minors

(11) Research institutions

(12) Institutions providing samples

(13) Collaborative research institutions

(14) Outside organizations

(15) Ethics committee

(16) Investigators

(17) Principal investigator

(18) Staff investigators

(19) Donors

(20) Genetic counseling

(21) Stored samples for clinical purposes

(22) Human cell/gene/tissue banks

VII. Detailed regulations

15. Detailed regulations

VIII. Effective date

16. Effective date

Preamble

The promotion of scientific research is the pivot of the realization of a society where people can live a healthy and fulfilling life. The research on the human genome/genes, which was initiated in the last half of the 20th century, has contributed greatly to the advancement of life science and healthcare sciences, and is about to play an important role in the improvement of health and well-being of the mankind, development of new industries and so forth.

Human genome and genes research depends heavily on research involving human subjects. The genetic information obtained in the research process reveals not only the genetic predisposition of the donor (person who contributed samples for use in the research on the human genome/genes) but also of his/her blood relatives. For this reason, a variety of ethical, legal and social issues have arisen concerning the handling of genetic information. Thus, it is essential to carry out the research appropriately, respecting human dignity and human rights and making efforts to promote public understanding and cooperation. To achieve this purpose, the human rights of individual donors must be protected on the basis of the ethical code stipulated, for example, in the Declaration of Helsinki by the World Medical Association, in preference to scientific or social benefits. In addition, status of research has to be fully explained to society, and research should be carried out based on public understanding. However, in Japan, no social norm has been established that can sufficiently respond to the requirements described above regarding research on the human genome/genes in general. Therefore, it was an urgent task to draw up substantial ethical guidelines for conducting research, respecting human dignity and securing the human rights of donors, their families and blood relatives.

These guidelines were established based on the principle described in the "Fundamental Principles of the Research on the Human Genome" (Executive summary by the Bioethics Committee, the Council for Science and Technology, dated June 14, 2000), which followed the "Universal Declaration on the Human Genome and Human Rights" by the United Nations Educational, Scientific and Cultural Organization (UNESCO), in reference to the "Guidelines for Taking Measures for Ethical Issues Accompanying Gene Analysis" (Executive summary by the Advanced Medical Technology Evaluation Subcommittee, Council of Health Sciences, dated April 28, 2000). These guidelines have been drawn up jointly by the Ministry of Education, Culture, Sports, Science and Technology, the Ministry of Health, Labor and Welfare, and the Ministry of Economy, Trade and Industry, and are to be applied to every research on the human genome/genes as an ethical guideline set out in society.

All investigators involved in the research on the human genome/genes are required to observe these guidelines.

<Note>

The "Guidelines for Taking Measures for Ethical Issues Accompanying Gene Analysis" has been integrated into these guidelines and will be abolished upon enforcing these guidelines.

I. Basic perspectives

1. Basic policy

These guidelines have been established based on characteristics of research on the human genome/genes, as an ethical guideline to be applied to all the human genome/gene analyses and to be observed at the research site. These guidelines aim to promote appropriate research, while respecting human dignity and human rights and promoting public understanding and cooperation. The basic policy of these guidelines is as follows.

<Note>

Since the genetic information obtained through the research on the human genome/genes may reveal the genetic predisposition of donors and of their family members and blood relatives, these guidelines take into consideration the various issues raised by this research and defines the projects to which these guidelines apply and specifies the scope of application (in Section 14 (3)).

(1) Respect for human dignity

(2) Investigators' sufficient explanation in advance and donor's free and voluntary consent.

(3) Thorough protection of personal information

(4) To implement socially beneficial research contributing to the basic intelligence, health and well-being of human beings.

(5) Priority is given to the protection of the human rights of each donor over the scientific and social benefits.

(6) To prepare a research protocol on the basis of these guidelines and to comply with the guidelines. To assure the appropriateness of the research by obtaining approval by an independent ethics committee that examines the research protocol.

(7) Assuring the transparency of the research through site investigation on the implementation status of the research by a third party and through publication of the research outcome.

2. Scope of application of these guidelines

These guidelines cover the research on the human genome/genes and seek the compliance of the investigators who are involved in this research.

<Detailed Regulation 1 (Detailed regulations regarding the projects started before the implementation of these guidelines)>

These guidelines do not cover the research on the human genome/genes that was initiated before the implementation of these guidelines and is still ongoing. However, even in this case, it is expected to carry out the research appropriately by following these guidelines to the extent possible.

<Detailed Regulation 2 (Detailed regulations regarding the collaborative research with foreign investigators)>

1. When conducting collaborative research with foreign research institutions, the viewpoints specified in these guidelines, such as the handling of the samples provided and the significance of the research on the human genome/genes, should also be observed in the part of the collaborative research conducted in the foreign country, in order to secure human dignity and human rights.
2. The research must be conducted in principle according to the standards stipulated in these guidelines, while observing the laws and guidelines of the foreign investigator's country.
3. When the standards of the foreign investigator's country are stricter than those set out in these guidelines, the research must be carried out in compliance with the stricter standards.

These guidelines do not apply to the laboratory tests and equivalent analysis of human genome/genes that are conducted during a medical examination and their results have been proved to be directly available in medical practice for donors and his/her blood relatives. However, as a matter of medical care, this issue requires careful inquiry. It is expected that this type of analysis on the human genome/genes is also handled appropriately with the responsibility of the physician in charge, taking into consideration the policy of this guideline and referring to other guidelines prepared by the medical societies concerned.

II. Responsibilities of investigators

3. Basic responsibilities of all investigators

(1) Investigators must conduct research on the human genome/genes, aiming at identifying biological phenomenon, preventing against diseases, improving diagnostic and treatment methods, health promotion, and so on.

(2) Investigators must confirm the social benefit of the research on the human genome/genes and ensure that the protection of the human rights of individuals is not overridden by scientific or social benefits.

(3) Investigators must bear in mind that it is essential to provide explanation on research design to potential donors or their proxy consent and to obtain consent prior to the implementation of the research on the human genome/genes.

(4) Investigators are prohibited from disclosing the personal information obtained through their duties without valid reasons. This also applies after resigning from the post.

(5) Investigators must ensure that personal information is secure and respond honestly to complaints regarding the handling of personal information.

(6) Investigators must promptly report any serious concern from the standpoint of human rights protection, such as an unexpected leak of personal information to the head of research institution and the principal investigator.

(7) Investigators must conduct research on the human genome/genes appropriately, while respecting human dignity and human rights, in compliance with these guidelines, which require that research only be implemented after obtaining the approval by the ethics committee and that it be conducted in compliance with the research protocol approved by the head of the research institution.

(8) Investigators must endeavor to assure research transparency of the research, for example by establishing the appropriate protocols for implementing the research, being subjected to site investigation by outside experts, responding appropriately to the inquiries of donors, and publishing the research results.

(9) Investigators must bear in mind that donation of samples is based on a bona-fide, and therefore must endeavor to minimize the requirement for human samples, for example, by appropriately preserving samples already obtained and deriving the most benefit from them.

4. Responsibilities of the head of research institution

(1) The head of the research institution has the overall responsibility for implementing the research on the human genome/genes in the institution. The head of the research institution must ensure that the principal investigator and staff investigators carry out the research appropriately according to the research protocol. Upon implementing the research, the head of the research institution must ensure that the employees are fully aware of the

following matters: The human rights of donors, and so on, must be protected to the fullest extent; Punitive actions, such as disciplinary measures, may be taken in the case of violations of these guidelines, research protocol, and so on.

<Detailed regulations regarding the exemplification of the head of research institution>

The following positions are examples of a head of a research institution.

- The director in the case of a hospital
- The director in the case of a health care center
- The dean of the medical school in the case of a university medical school
- The director in the case of a research institute of enterprise

(2) The director of the research institution must take adequate measures to prevent the leak of personal information.

<Detailed regulations regarding the measures to be taken for the protection of personal information>

The procedure, facility and system for strict management of personal information should be prepared. For example, computers that are used to process personal information should be separated from any other computer, and other appropriate measures should be taken.

(3) The head of a research institution where personal information is handled, such as an institution providing samples, must nominate a person to be in charge of personal information management in order to ensure the protection of personal information in the research on the human genome/genes. In addition, according to need, co-manager or assistant can be positioned after the line of command has been established. Assistants carry out the actual operations under the supervision of the personal information manager.

<Detailed regulations regarding the requirements of personal information manager>

1. The personal information manager and co-manager should be those who are prohibited from leaking the personal information obtained through their responsibilities (physicians, pharmacists, etc.) under Article No. 134 of the Penalty Code (Act No. 45. of 1907), Article No. 100 of the National Public Service Law (Act No. 120. of 1947), and other laws.
2. The personal information manager and co-manager cannot double with the principal investigator or staff investigator who carries out the research (except for the operation of

providing samples) on the human genome/genes using the samples contributed.

(4) The head of the research institution must set up an ethics committee as an advisory body to assess the propriety of implementing the research on the human genome/genes. However, when this is difficult due to the small scale of the institution providing the samples, the ethics committee can be substituted by an ethics committee that was set up by a collaborative research institution, public-service corporation or scientific society.

<Detailed Regulation 1 (Detailed regulations regarding the establishment of an ethics committee)>

It is acceptable that a kindred committee already established in the research institution is reorganized into an ethics committee complying with these guidelines. In this case, the actual name of the committee is not important.

<Detailed Regulation 2 (Detailed regulations regarding the handling of collaborative research)>

In the case of collaborative research, it is a principle that the research protocol is approved by the ethics committee established in each research institution. Upon discussing the propriety of implementing the research, the head of the research institution must obtain important information including the approval status of the research protocol in the partner institution, acquisition of informed consent, and the status of anonymity, and provide the information to the ethics committee of the research institution.

(5) The head of the research institution must decide whether or not to approve the research protocol and its amendment for all of the protocols, respecting the opinions of the ethics committee. In this case, the head of the research institution should not approve the implementation of research that was not approved of by the ethics committee.

(6) The head of the research institution must grasp the implementation status of the research on the human genome/genes by receiving periodic reports from the principal investigator at least once a year and through periodic site investigation conducted by outside experts at least once a year. The head of the research institution must also order alteration of research protocol or termination of research according to need or based on the decision of the ethics committee.

<Detailed regulations regarding site investigation by outside experts>

1. The head of the research institution must give directions to conduct site investigation in

order to confirm that the process of obtaining informed consent and the protection of personal information are carried out properly according to the research protocol.

2. The head of the research institution must direct the principal investigator and the staff investigators to cooperate in the site investigation.

3. The outside person in charge of the investigation is prohibited from disclosing the information obtained through the site investigation without valid reasons. This also applies after resigning from the post.

(7) The head of the research institution must send the copies of the following documents to the personal information manager: the approved research protocol, the periodic reports on the research implementation status, and the outcome of the site investigation conducted by outside experts.

(8) The head of research institution must send the copies of the following documents to the ethics committee: the periodic reports on the research implementation status, and the outcome of the site investigation conducted by outside experts.

(9) The head of the research institution must respond appropriately to the complaints and inquiries from the donors, etc., by setting up a complaints window, etc.

(10) The head of an institution providing samples must in principle ensure the anonymity of the samples upon providing them to outside organizations (When an institution providing samples carries out the research on the human genome/genes, the research unit is regarded as an outside organization.).

<Detailed regulations on providing non-anonymous samples to outside organizations>

The provision of non-anonymous samples is permitted when all of the following requirements are met: the donor or his/her proxy consent gives consent to provide non-anonymous samples to outside organizations; approval from the ethics committee is obtained; the research protocol approved by the head of the institution allows the provision of non-anonymous samples to outside organizations.

(11) The head of an institution providing samples must make arrangements, according to need, so that the donor and his/her family and blood relatives can receive genetic counseling. This should be done by establishment of genetic counseling service or an explanation about genetic counseling and introduction of an appropriate facility.

<Detailed regulations regarding introducing a facility that provides genetic counseling>

If no genetic counseling service is available in the institution providing samples, an appropriate facility for the counseling should be introduced to the donor and his/her family and blood relatives upon request.

5. Responsibilities of the principal investigator

(1) The principal investigator must prepare the research protocol and obtain the approval of the head of the research institution prior to the implementation of the research on the human genome/genes and when making alterations to the research plan.

(2) The principal investigator must give sufficient consideration to the necessity for the research and search for research methods that allow the donors to avoid disadvantages. This includes consideration of various foreseeable impacts on the donors involved in the research of the human genome/genes to be implemented.

<Detailed regulations regarding donors with diseases accompanying mental disorder, intellectual impairment, etc.>

If the donor has a monogenic disease, etc. for which no treatment or preventive measure has been established and that is accompanied by mental disorder, intellectual impairment or serious physical disabilities, the principal investigator must assess with special caution the necessity for the research, the medical and mental impacts on the donor, the research method taking into consideration these impacts, and others. Moreover, the ethics committee must examine these issues with special caution.

(3) The principal investigator must prepare the research protocol, giving full consideration to the special nature of the research on the human genome/genes. The following matters must be particularly clearly stated, the procedure and method for obtaining informed consent, measures to protect personal information, expected results of the research and policy of their disclosure; storage of the samples and the procedure for usage; policy on genetic counseling.

<Detailed regulations regarding the matters included in the research protocol>

In general, the matters to be included in the research protocol are as follows, although changes can be made according to the nature of the research.

• The policy to select donors (specific method of selection reflecting a rational selection

of donors; procedure of informing the donor of the name of the disease or of corresponding conditions of the disease in the case of selecting donors with diseases or abnormal drug responses, etc.).

• The objectives, significance, and method of the research (the diseases to be studied, analysis method, etc.; possible additions and changes to those, if any, expected in future; in the case of monogenic diseases or the like, the addition of special notes describing the necessity of the research and the measures taken to avoid disadvantaging the donor), the duration of the research, foreseeable outcomes and risks, and the measures taken to protect personal information (including the handling of cases that have not been made anonymous).

• The type and quantity of the samples

• Names of collaborative research institutions

• Name of the principal investigator, etc.

• The procedure and method for obtaining informed consent

• Written information and Informed Consent Form for obtaining informed consent

• In case of difficulty in obtaining written informed consent from the donor, explanation of the significance of the research, why the research cannot be undertaken without obtaining a sample from the donor, why the prospective donor has been selected, and why the representative of proxy consent is nominated.

• Policy on the disclosure of genetic information

• Whether the donor's consent has been obtained or not in the case of using existing samples obtained before implementation of the research, details of use and timing of the sample obtained, and compliance with these guidelines.

• The contents of the Informed Consent Form in the case of obtaining samples or genetic information from other research institutions.

• Matters including the contents of the contract and the method of ensuring anonymity, in the case of providing samples or genetic information to outside organizations or in the case of conducting a part of research as a contract research at other institutions.

• Storage requirements of the samples (including information on whether the sample may be used for other research and the nature of that research.).

• The name of the bank, method of providing anonymity, etc. in the case of providing human cell/gene/tissue banks with samples .

• Disposal of samples, and anonymity at disposal

• Necessity of genetic counseling and availability of the counseling service.

• Source of research funds

(4) The principal investigator must supervise the investigators to ensure that research on the human genome/genes is conducted appropriately by ensuring, for example, that all observe the matters specified in the approved research protocol.

(5) The principal investigator must report periodically, at least once a year, in writing to the head of the research institution the state of implementation of the research on the human genome/genes.

<Detailed regulations regarding matters to be reported>

In general, the periodic report to the head of the research institution from the principal investigator should include the following, although changes can be made according to the nature of the research.

- Number of samples provided
- Number of samples or pieces of genetic information supplied to outside organizations, and the reason for their supply.
- Number of samples used for the research on the human genome/genes.
- Research results and research progress
- Presence or absence of any problems
- For the institutions providing samples, the number of anonymous samples should be reported in addition to the matters described above.

(6) The principal investigator must conduct the research on the human genome/genes using in principle anonymous samples and genetic information.

<Detailed regulations regarding research conducted under non-anonymous conditions>

Making the samples or genetic information anonymous is not necessary if the donor or his/her proxy consent gives consent and if the use of non-anonymous samples is allowed in research protocol approved by the head of the research institution following approval by the ethic committee.

(7) The principal investigator is prohibited in principle from supplying non-anonymous samples or genetic information to outside organizations.

<Detailed regulations on supplying samples and genetic information to outside organizations under non-anonymous conditions>

It is acceptable to provide non-anonymous samples or genetic information to outside organizations if the donor or his/her proxy consent gives consent and if the release of non-anonymous samples is allowed in the research protocol approved by the head of the research institution following approval by the ethics committee.

(8) The principal investigator must in principle make anonymous the samples or genetic information in the case of contracting part of the research on the human genome/genes to other institutions.

<Detailed regulations on contracting research using non-anonymous samples to other institutions>

Anonymity of the samples and genetic information is not necessary if the donor or his/her proxy consent gives consent and if the use of non-anonymous samples is allowed in the research protocol approved by the head of the research institution following approval by the ethics committee.

(9) The principal investigator must, on regular basis or upon the donor's request, either explain clearly or publicize the progress status and results of the research on the human genome/genes. However, this does not apply to the part of the research information that needs to be kept confidential to protect of human rights of the donors and intellectual property of the researchers.

6. Responsibilities of the personal information manager

(1) Personal information manager (including co-manager, to whom the same guidelines apply) must in principle make anonymous samples and genetic information prior to implementing research on the human genome/genes when requested by the principal investigator. In the case when the anonymization is performed by the investigators, who act as assistants to the personal information manager, the personal information manager must supervise the anonymizing process.

<Detailed regulations regarding exceptions to anonymity of the samples>

Ensuring that anonymity of the samples is not necessary if the donor or his/her proxy consent gives consent and if the use of non-anonymous samples is allowed in the research plan approved by the head of the research institution following approval by the ethics committee.

(2) The personal information manager is in principle prohibited from providing

outside organizations with information protected by anonymity .

<Detailed regulations on providing outside organizations with personal information>
Personal information can be supplied to outside organizations if the donor or his/her proxy consent gives consent and if the use of non-anonymous samples is allowed in the research protocol approved by the head of the research institution following approval by the ethics committee.

(3) The personal information manager must execute strict control of personal information to prevent leakage, by performing the anonymization and by appropriately supervising investigators who use non-anonymous samples.

7. Responsibilities and membership of ethics committee

(1) The ethics committee must assess both the scientific and ethical propriety of the research protocol on the basis of these guidelines, and submit its assessments in written form to the head of the research institution.

(2) The ethics committee is entitled to offer its opinion concerning research in progress. This may include recommending to the head of the research institution that changes to made to the research protocol or even, in some cases, that the research be discontinued.

(3) The ethics committee is prohibited from disclosing information obtained through its responsibilities without valid reason. This prohibition continues to apply after resignation from the post.

(4) The ethics committee must be comprised of members with multidisciplinary and pluralistic backgrounds and operate properly so that it can make fair and unbiased assessment from an independent standpoint.

<Detailed Regulations 1 (Detailed regulations regarding the composition of the ethics committee)>

• The ethics committee must be comprised of the members in the field of the humanities and social science, including experts in ethics and law, natural science experts, and others representing the general public.

• It is expected that extramural members account for more than half of the committee members. If this is difficult to achieve, the committee must include at least 2 or more

extramural members.

• More than half of extramural members must come from either in the fields of humanities/social sciences or representative of general public.

• The committee must be comprised of both genders.

<Detailed Regulations 2 (Detailed regulations on operating the ethics committee)>

• At least one expert in the field of humanities or social scientist, and one citizen member must participate in discussion or voting.

• The head of the research institution as well as the principal investigator and staff investigators of the research to be reviewed should not participate in the discussion or voting. However, they can attend meetings upon the request of the ethics committee for explanation.

<Detailed Regulations 3 (Detailed regulations regarding rules for operating the committee)>

The rules for operating the committee are stipulated regarding the following matters.

• Method for selecting the chairperson

• Requirements for effecting a meeting

• Voting method

• Storage period of examination records

• Matters concerning disclosure

分担研究報告書
（１－１）

平成13年度厚生科学研究費補助金（ヒトゲノム・再生医療等研究事業）
分担研究報告書

「倫理委員会」の起源と問題点

研究協力者　土屋貴志　大阪市立大学大学院文学研究科
分担研究者　白井泰子　国立精神・神経センター精神保健研究所

研究要旨

米国における「倫理委員会」の系統・起源および役割について説明し、日本の「倫理委員会」の現状を粗描して、その問題点を指摘した。

米国の「倫理委員会」には大きく分けて、人体実験（人間を被験者とする実験・研究）の審査を行う「施設内審査委員会」と、技術的にはルーティン化しているが是非の判断が難しい医療行為について審議・助言などを行う「病院倫理委員会（施設内倫理委員会）」の二つの系統がある。

施設内審査委員会は、被験者の人権を護るために、米連邦政府が研究を助成する際の遵守条件として、各機関が自ら研究内容の審査を行うよう求めた行政規則に基づく。一方、病院倫理委員会は、裁判所や政府委員会・医師会・医学系学会等によって設置が推奨され、生命維持治療の停止問題などについて審議・助言するほか、医療機関の方針決定や医療スタッフの教育も行っている。

日本では、倫理委員会が米国の施設内審査委員会に相当する役割を主に果たしているが、米国における二つの系統の区別が自覚されておらず、病院倫理委員会の役割は等閑視されている。しかも、人体実験を包括的に議論する枠組が存在しないので、研究審査の目的および必要性が明確に認識されていない。また、各施設の倫理委員会が研究審査を行う際の標準が示されておらず、審査項目および審査基準が施設ごとにまちまちになる可能性がある。さらに、中央の監督機関や罰則を伴う規則がなく、被験者の人権を保障する制度が整っていない。

1.「倫理委員会」の二つの文脈

米国では、いわゆる「倫理委員会」は二つの系統に大きく分かれている[註1]。第一の系統は「施設内審査委員会(Institutional Review Board, IRB)」であり、これは「人体実験」すなわち《人間を被験者とする実験ないし研究》を審査するために設けられている。こういう人体実験には医学研究だけでなく、行動科学や社会科学の研究で人間を被験者とするものも含まれる。また、人体実験は、被験者に医学的利益がある可能性があるもの（治療的実験）と、被験者に医学的利益はないもの（非治療的実験）に分けられる。

第二の系統は「病院倫理委員会(Hospital Ethics Committee, HEC)」ないし「施設内倫理委員会(Institutional Ethics Committee, IEC)」で、これは生命維持治療の停止など、技術的には成熟しルーティン化している医療行為のうち是非の判断の難しい事例について審議・助言などを行うために設けられている。

生殖技術・臓器移植・遺伝子治療などのいわゆる「先端医療」は、たとえ被験者に大きな医学的利益が見込まれる治療的実験であっても、まだ実験的性格が強く研究段階にあるうちは、病院倫理委員会ではなく、施設内審査委員会で取り扱われる。

2. 日本の「倫理委員会」の現状

日本最初の医学系倫理委員会は 1980 年 11 月 17 日に発足した「札幌医科大学臨床

研究調整委員会」であるが、体外受精の臨床応用について審議するために 1982 年 12 月 9 日に設置された徳島大学医学部倫理委員会が、外部委員を入れ審議を公開するなど、初めての本格的な倫理委員会である[2)3)4)]。

その後相次いで各地の医科大学や大学医学部に設けられた倫理委員会の審査課題をみると、体外受精、脳死移植、女児生み分け、生体肝移植、遺伝子治療、治験など、先端医療研究の審査がそのほとんどを占めている[2)5)]。これは、人体実験の原則を定めた世界医師会の「ヘルシンキ宣言」が 1975 年の修正以降「特別に任命された独立した委員会」での審査を必須とし、委員会に承認された研究成果でなければ国際的雑誌に受理されないようになったことの影響も大きいと思われる。

このように、日本の「倫理委員会」は、米国の施設内審査委員会に相当する役割、すなわち医学実験ないし研究について審査する役割を主に果たしてきたといえる。しかしながら、そうした研究審査がそもそも何のために必要とされたのかについては、あまり理解されていないようにみえる。また、米国における病院倫理委員会の機能は、エホバの証人の輸血拒否問題を例外として、ほとんど果たされていない。

3. 米国の「倫理委員会」の起源と役割

(1) 施設内審査委員会[6)7)8)9)]

施設内審査委員会は、被験者の人権を侵害した人体実験スキャンダルに対する米国の政策的対応の中から生まれてきた。すなわち、人体実験の審査は、第一に被験者の人権を護るために必要とされたのである。具体的には、米連邦政府が人間を被験者とする研究に資金援助する際の遵守条件として、施設内審査委員会による審査を求めた。

施設内審査委員会は、研究者同士の同僚審査 (peer review) を原型としている。連邦政府によるその最初の規定は、医学研究機関の一大複合体である国立保健研究所 (National Institutes of Health, NIH) が研究病院である臨床センター (Clinical Center) を開設した 1953 年に定めた"Group Consideration for Clinical Research Procedures Deviating from Accepted Medical Practice or Involving Unusual Hazard"である。これは、すべての被験者から IC を得ること、非治療的研究や危険性の高い研究は、臨床センターと他の NIH 施設から選出された委員からなる「臨床研究委員会 (Clinical Research Committee)」の審査を受けること、危険性の高い研究の被験者からは書面の同意を得ること、などを義務づけた[9)]。しかしこの規定は臨床センターで行われる研究にしか適用されなかった。

1963 年には、テュレイン大学のチンパンジー腎異種移植と、末期患者にがん細胞を注射したユダヤ人慢性疾患病院における免疫研究が問題になり、その両方に資金援助していた NIH と公衆衛生局 (Public Health Service, PHS) は、人間を被験者とする研究の規制へと乗り出す。1966 年、PHS 長官 (Surgeon General) は政策声明を出し、PHS の資金援助を受ける米国内のすべての施設に対し、人間を被験者とするあらゆる研究を申請する際には、施設の同僚によって構成される委員会による事前審査について記載するよう求めた。こうして全米レベルで委員会による研究審査体制が定められた。

ただし、1968 年の時点では 73 % (142 施設中 104 施設) の委員会が科学者と医師のみで構成されていた。こうした状況は 1969 年の PHS の指針で不適切とされ、非医学者や他の分野の研究者、ならびにその施設に所属しない部外者を入れることが求められるようになる。