研究者等は、研究の結果を公表するときは、個々の研究対象者を特定できないようにしなければならない。

When researchers publish study findings, appropriate precautions should be taken to guarantee that the identities of individual human subjects can not be traced.

## 第５　用語の定義

## CHAPTER 5. DEFINITION OF TERMS

### 13　用語の定義

### SECTION 13. DEFINITION OF TERMS IN THESE GUIDELINES

（１）疫学研究

明確に特定された人間集団の中で出現する健康に関する様々な事象の頻度及び分布並びにそれらに影響を与える要因を明らかにする科学研究をいう。

(1) Epidemiological research

Epidemiological research refers to scientific research elucidating the prevalence and distribution of various health related conditions in a well defined population, and identifying the factors influencing them.

＜細則＞

1　医師等が、主に、自らの又はその属する病院若しくは診療所の今後の診療に反映させるため、所属する機関が保有する、診療記録など人の健康に関する情報を縦覧し知見を得る行為は、この指針でいう疫学研究には該当しない。

2　市町村、都道府県、保健所等が地域において行う保健事業や、産業保健又は学校保健の分野において産業医又は学校医が法令に基づ

*(Provisions)*

*1. Clinician's review and analysis of medical records stored in their institutions for the primary purpose of treatment are not considered epidemiological research defined under these Guidelines.*

*2. Preventive medical activities conducted by municipal governments, prefectural governments and public health centers, surveys conducted by*

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| くその業務の範囲内で行う調査、脳卒中情報システム事業やいわゆるがん登録事業等は、この指針でいう疫学研究には該当しない。 | *occupationalhealth physicians or school health physicians within their official capacities, and reporting systems such as cancer registry or apoplexy registry are not considered as epidemiological research defined under these Guidelines.* |
| （２）介入研究<br>疫学研究のうち、研究者等が研究対象者の集団を原則として２群以上のグループに分け、それぞれに異なる治療方法、予防方法その他の健康に影響を与えると考えられる要因に関する作為又は不作為の割付けを行って、結果を比較する手法によるものをいう。 | (2) Interventional Studies<br>Interventional studies are a category of epidemiological research in which researchers divide a defined population into two or more subgroups, assigning them different treatments, preventive measures or other factors affecting health, for comparative analyses. |
| （３）観察研究<br>疫学研究のうち、介入研究以外のものをいう。 | (3) Observational Studies<br>Observational studies are epidemiological research other than interventional studies. |
| （４）資料<br>疫学研究に用いようとする血液、組織、細胞、体液、排泄物及びこれらから抽出したＤＮＡ等の人の体の一部の試料並びに診断及び治療を通じて得られた疾病名、投薬名、検査結果等の人の健康に関する情報その他の研究に用いられる情報（死者に係るものを含む。）をいう。 | (4)Material(s)<br>Material(s) used for epidemiological research refer to any part of the human body including blood, tissues, cells, bodily fluids, excrement, and human DNA as well as personal health data such as diagnoses, medication and laboratory findings. Material(s) include human biological specimens from living and nonliving individuals. |

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| （５）個人情報<br>個人に関する情報であって、当該情報に含まれる氏名、生年月日その他の記述等により特定の個人を識別することができるもの（他の情報と容易に照合することができ、それにより特定の個人を識別することができることとなるものを含む。）をいう。 | (5) Personal Data<br>Personal data refers to information concerning specific individuals identifiable by using personal information such as name, date of birth, or other description. Personal data also includes any information which can easily be matched with other information and can identify specific individuals. |
| （６）匿名化<br>個人情報から個人を識別することができる情報の全部又は一部を取り除き、代わりにその人と関わりのない符号又は番号を付すことをいう。資料に付随する情報のうち、ある情報だけでは特定の人を識別できない情報であっても、各種の名簿等の他で入手できる情報と組み合わせることにより、その人を識別できる場合には、組合せに必要な情報の全部又は一部を取り除いて、その人が識別できないようにすることをいう。 | (6) Anonymizing<br>Anonymizing refers to removing identifiers from personal data and replacing them with codes unlinked to a person's identity. Where personal data might not be identifiable per se, but can nevertheless be made identifiable by correspondence with other readily available data, such as directories, it is necessary to remove all or part of the linking information. |
| （７）連結不可能匿名化<br>個人を識別できないように、その人と新たに付された符号又は番号の対応表を残さない方法による匿名化をいう。 | (7) Unlinkable Anonymizing<br>"Unlinkable anonymizing" refers to a form of anonymizing, without any matching links to personal data with codes (such as corresponding tables). |

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| （８）研究者等<br>研究責任者、研究機関の長その他の疫学研究に携わる関係者（研究者等に対し既存資料等の提供を行う者であって、当該提供以外に疫学研究に関与しないものを除く。）をいう。 | (8) Researchers<br>Researchers include principal investigators, institute heads and other persons involved in conducting epidemiological research (excluding those who simply supply stored materials with no further involvement in epidemiological research). |
| （９）研究責任者<br>個々の研究機関において、疫学研究を遂行するとともに、その疫学研究に係る業務を統括する者をいう。 | (9) Principal Investigators<br>Principal investigators refer to researchers who conduct and supervise the entire epidemiological study at each research institute. |
| （10）研究機関<br>疫学研究を実施する機関（研究者等に対し既存資料等の提供を行う者であって、当該提供以外に疫学研究に関与しないものの所属する機関を除く。）をいう。 | (10) Research Institute<br>Research institute refers to organizations that conduct epidemiological research (excluding organizations which simply supply stored materials with no further involvement in epidemiological research). |
| （11）共同研究機関<br>研究計画書に記載された疫学研究を共同して行う研究機関をいう。 | (11) Collaborating Research Institute<br>Collaborating research institute refers to research institutes specified in a research proposal as collaborating in an epidemiological study. |
| （12）倫理審査委員会<br>疫学研究の実施の適否その他疫学研究に関し必要な事項について、研究対象者の個人の尊厳及び人権の尊重その他 | (12) Ethics Review Committee<br>Ethics review committee refers to a consultative panel, organized by the institute head, with the mandate of reviewing the appropriateness of an |

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| の倫理的観点及び科学的観点から調査審議するため、研究機関の長の諮問機関として置かれた合議制の機関をいう。 | epidemiological study, particularly issues related to the ethical and scientific aspects protecting human rights and dignities of research subjects. |
| (13) インフォームド・コンセント<br>研究対象者となることを求められた人が、研究者等から事前に疫学研究に関する十分な説明を受け、その疫学研究の意義、目的、方法、予測される結果や不利益等を理解し、自由意思に基づいて与える、研究対象者となること及び資料の取扱いに関する同意をいう。 | (13) Informed Consent<br>Informed consent refers to consent given by prospective research subjects for participation in a study and/or to allow one's biological material or personal data to be used in a study. Consent should be based on one's own free will and cognizance of the significance, purpose, methods, expected outcomes and potential risks of the epidemiological research proposed, after being adequately briefed by the researcher. |
| (14) 既存資料等<br>次のいずれかに該当する資料をいう。<br>① 疫学研究の研究計画書の立案時までに既に存在する資料<br>② 疫学研究の研究計画書の立案時以降に収集した資料であって収集の時点においては当該疫学研究に用いることを目的としていなかったもの | (14) Stored Material(s)<br>Stored material(s) refers to either:<br>a) Material(s) already collected prior to research proposal.<br>b) Material(s) to be collected after research proposal, but not intended to be used for the proposed epidemiological study. |

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| **第６　細則** | # CHAPTER 6. SPECIFICATIONS |
| 14　**細則** | ## SECTION 14. SPECIFICATIONS |
| **この指針に定めるもののほか、この指針の施行に関し必要な事項は、別に定める。** | Further specifications will be defined for implementation of the Guidelines. |
| **第７　見直し** | # CHAPTER 7. REVISIONS |
| 15　**見直し** | ## SECTION 15. REVISIONS |
| **この指針は、必要に応じ、又は施行後５年を目途としてその全般に関して検討を加えた上で、見直しを行うものとする。** | These Guidelines shall be revised as necessary, or minimally within 5 years after their implementation with thorough examination of the whole contents. |
| **第８　施行期日** | # CHAPTER 8. IMPLEMENTATION |
| 16　**施行期日** | ## SECTION 16. IMPLEMENTATION |
| **この指針は、平成 14 年７月１日から施行する。** | These Guidelines shall take effect on 1 July 2002. |
| ＜細則＞<br>指針施行前に着手された疫学研究に対してはこの指針は適用しないが、可能な限り、この指針に沿って適正に実施することが望まれる。 | *(Provisions)*<br>*Epidemiological studies which were started prior to the implementation of the Guidelines will be exempted, nonetheless fair compliance with these Guidelines is advocated.* |

# ETHICAL GUIDELINES FOR EPIDEMIOLOGICAL RESEARCH

17 June 2002

Ministry of Education, Culture, Sports, Science and Technology

Ministry of Health, Labour and Welfare

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# Preamble

Epidemiological research entails studies of the distribution and determinants of disease and health related conditions affecting specific populations, and the application of studies to control health problems and events, in the effort to advance both medicine and the promotion of better health. Epidemiological research is essential to identify the causes of disease, to examine the efficacy of treatments and preventive measures, and to elucidate their relationships. Increased awareness of the incidence and prevalence of disease and health threats is essential for more effective prevention and treatment of disease, and for elucidating environmental, behavioral and biological factors associated with health conditions.

Epidemiological research can involve extensive data on research subjects and related physical, environmental and behavioral factors, frequently utilizing multidisciplinary approaches and researchers from various health professions.

In view of the expanding scope of epidemiological research methods and data acquisition, increased societal concerns for the rights and freedoms of research subjects and privacy protection are being addressed with the adoption of informed consent policies and more explicit guidelines for conducting research.

The following guidelines (hereinafter, the Guidelines) have been formulated for adoption, to duly protect the rights and privacy of research subjects, and to provide a standard for ethical dignity and professional conduct in epidemiological research and practice.

The Guidelines mandate the general practice of informed consent for research subjects of all epidemiological studies, according to the principles of the Declaration of Helsinki, adopted by the World Medical Association. In consideration of the diverse

approaches to epidemiological research, the Guidelines profile the basic principles ethics review committees should adopt in the evaluation of proposed studies and protocols, allowing discretionary application under special or extraordinary conditions.

Investigators are expected to conduct all epidemiological research in accordance with the Guidelines, unless deemed impractical by extraordinary circumstances, in order to advance high professional standards in both humane attitudes and quality of research, as well as to foster public confidence, support and participation in related epidemiological programs, in the efforts to provide improved community health conditions and promote public health issues.

# CHAPTER 1. BASIC PRINCIPLES

## SECTION 1. PURPOSE

All epidemiological research practices should be conducted in accordance with the principles defined in these Guidelines, established as the standards for all persons for better involved in epidemiological research. The Guidelines shall regulate appropriate conduct in epidemiological research for better public understanding and support, and address ethical issues protecting individual freedoms and privacy rights as well as scientific conduct, the importance of epidemiological research in public health as well enclosing as academic freedom.

## SECTION 2. JURISDICTION OF GUIDELINES

The Guidelines present the set of ethical standards that shall be applied to studying the etiology of human disease, and improving prophylactic, diagnostic and therapeutic procedures. Researchers and others dealing with epidemiological issues should comply with these Guidelines, whereas the following types of studies are acknowledged exceptions:

1. Surveys conducted by legal authorization.

2. Epidemiological surveys of subjects whose identities are both anonymous and unlinkable.

3. Interventional studies involving medical procedures, such as surgery, medication, etc.

*(Provisions)*

*1. Exception (1) refers to surveys authorized by specific law. Examples include infectious disease surveillance pursuant to the "Infectious Disease Control and Medical Care Act".*

*2. Jurisdiction of the Guidelines is summarized as follows:*

*Examples for within jurisdiction of Guidelines*

*Collecting and analyzing patient medical information from multiple medical institutions with the specific purpose of estimating the numbers of individuals with a given disease, in efforts to better understand and evaluate treatment methods.*

*Supplying stored material(s) or material(s) extracted from stored material(s) is subject to Section 11, given that such practice is not considered research activity.*

*Examples for outside jurisdiction of Guidelines*

*Reviewing the medical records of various patients with a specific disease for the primary purpose of indicating treatment options for particular patients.*

*Collecting and analyzing medical records and other health-related patient information from a medical institution to which the researcher belongs, unrelated to patient treatment, and publishing research findings either within the institute or outside.*

*Examples for within jurisdiction of Guidelines*

*Studies involving subjects divided into two groups, one given a specific diet and the other given an ordinary diet, to examine the beneficial effects of a specific diet.*

*Examples for outside jurisdiction of Guidelines*

*Studies involving subjects divided into two groups, one given a specific drug and the other given a placebo, to examine the effects of a specific medication.*

*In clinical pharmaceutical trials, GCP (Good Clinical Practice, as defined by ministerial directive) shall be observed. (Unlinkable, anonymous data)*

*Analyzing the relationship between patient lifestyle-related disease and energy intake, on a regional basis, employing Patient Survey or National Nutritional Survey.*

*Examples for within jurisdiction of Guidelines*

*Developing prophylactic or preventative measures and elucidating geographical distribution of specific diseases using laboratory data or human specimens obtained by public health activities, including public registries for cerebral apoplexies and cancer. These Guidelines do not apply if a study is conducted as a public health activity.*

*Examples for outside jurisdiction of Guidelines*

*Public health activities conducted pursuant to law or other administrative orders.*

*3. In case stricter standards, if any, are applicable in partner countries of international cooperative projects, researchers shall abide by the stricter standards in addition to these Guidelines.*

## SECTION 3. BASIC RULES FOR RESEARCHERS

(1) Ensuring Scientific Soundness and Ethical Integrity in Epidemiology

1) Researchers shall conduct epidemiological studies with due consideration for the personal dignity and human rights of all subjects.

2) Researchers shall not conduct epidemiological studies which are not scientifically sound or ethical, and shall provide explicit, detailed research proposals that fully account for and address these issues.

3) Researchers shall obtain all appropriate permissions from the heads of their respective research institutes (institute head) for epidemiological study proposals and any modifications to research plans.

*(Provision)*

*Examples of institute heads include the following positions:*

- *hospitals: administrators;*
- *public health centers: director of the center;*
- *medical schools: school dean;*
- *corporate research institute: institute director.*

4) Researchers shall conduct epidemiological studies in compliance with all appropriate laws, these Guidelines, and the approved research proposal.

5) Researchers shall not select research subjects by inappropriate or arbitrary means.

(2) Protecting Personal Information

Researchers shall properly manage and protect the personal data of all research subjects.

(3) Informed Consent

1) Researchers, in principle, shall obtain written informed consent from all research subjects prior to conducting any epidemiological study.

2) Investigators shall stipulate in their research proposals:

a) how a study is explained to the subjects involved,

b) how informed consent will be obtained from subjects,

c) and any other relevant issues concerning informed consent.

(4) Publication of Study Findings

Principal investigators shall publish research findings after taking necessary measures to protect the privacy of research subjects.

## SECTION 4. RESPONSIBILITIES OF INSTITUTE HEADS

(1) Emphasizing Ethical Considerations in Research

Institute heads shall assure that researchers within their organizations are aware of the importance of respecting the personal dignity and human rights of research subjects, and that necessary measures are taken to protect the privacy of individuals in epidemiological studies conducted, by this means serving to avoid potential ethical, legal or communal disputes related to research studies.

(2) Establishing Ethics Review Committees

Institute heads shall establish ethics review committees in their institutes, to review the appropriateness of research proposals. The institute head shall delegate these review functions to out-of-house ethics review committees (established by a collaborating research institute, public corporation or academic organization), when the size of their institute is not large enough to warrant an independent ethics review committee.

*(Provision)*

*Out-of-house ethics review committees referred to in the second paragraph of this section include those established jointly by the heads of multiple collaborating research institutes.*

(3) Obligation of Ethics Review Committees

Institute heads shall seek evaluations from ethics review committees when epidemiological study proposals are put forward by researchers, pursuant to Sec.3(1)3).

(Provisions)

*1. Researchers who do not belong to a specific research institute shall be exempt from permission by institute head as specified in Sec.3(1)3), Sec.7, Sec.8, Sec.10(2), Sec11(1)(2)2)3).*

*2. Researchers who do not belong to a specific research institute are encouraged to voluntarily seek evaluations from an established institutional ethics review committee, to which collaborating researchers of the study belong (e.g., universities, public corporations or other academic institutions).*

(4) Permission by Institute Head

Institute heads shall decide whether to approve or disapprove a proposed epidemiological study respecting the opinions put forward by ethics review committees. Institute heads shall not give approval to applications in contradiction to the expressed opinions of the ethics review committee.

*(Provision)*

*Institute heads may choose to approve an epidemiological proposal if they determine the study needs to be carried out urgently to prevent or control a serious public health threat before evaluation by an ethics review committee can be performed. In such cases, institute heads shall seek an ERC opinion as soon as possible following approval of a research proposal, and ensure that the principal investigator suspends or modifies the study in accordance with the recommendations of the ethics review committee.*

# CHAPTER 2. ETHICS REVIEW COMMITTEES

## SECTION 5. ETHICS REVIEW COMMITTEES

(1) Organization and Obligations

1) When so requested by institute heads, ethics review committees shall assess research proposals considering both ethical and scientific perspectives, and provide written evaluation on how the proposal complies with these Guidelines and other research methodologies.

2) Ethics review committees shall be organized in a manner that assures fair and unbiased reviews, taking into account and representing the interdisciplinary and pluralistic viewpoints of committee members from various backgrounds.

*(Provision)*

*Ethics review committees shall be organized to include authorities, experts and professionals in both clinical and experimental medicine, as well as specialists in the social sciences (notably law), in addition to representatives of the general public. Committee membership should also be extended to outsiders (members who are not affiliated to the institute), and consist of both sexes.*

3) Members of ethics review committees shall not disclose confidential information obtained in the review process without appropriate reason either during and/or after their tenure.

(2) Reviewing Process by Ethics Review Committees

1) Committee members who have conflicts of interest related to research proposals should not be involved in the review process. This restriction, however, shall not prevent such members from attending the committee or giving an account of the proposals when requested.

2) Procedures of the review process, the names and credentials of members, and a summary of the review discussion should be disclosed to the public. However, confidential information pertaining to the rights and privacy of study subjects

and any intellectual property rights associated with the research proposal may remain confidential.

3) Ethics review committees may include a provision in their regulations and procedures allowing the institute heads the option to delegate review of the proposal, with respect to its adherence to these Guidelines and other methodology issues, to an alternative ethics review committee or appropriate academic body.

*(Provision)*

*An alternative ethics review committee or appropriate academic body may include those jointly established by the heads of multiple collaborating research institutes.*

4) Ethics review committees may include a provision in their regulations and procedures allowing for a summary (expedited) review for minor agendas conducted, for example, by a single member of the committee appointed by a committee chairperson. These summary reviews should be provided to all other committee members.

*(Provision)*

*Minor agendas which are eligible for summary review are generally defined as:*

*1- Minor alterations in research proposals;*

*2- Review of a research proposal to be conducted as part of a collaborative study, when ethics review committee approval is already given by the principal investigator's institute;*

*3-Review of a research proposal that does not exceed minimal risk for subjects in the study. Minimal risk refers to risks within the normal range of physical, psychological and social hazards likely encountered in daily living or routine medical exams, and which are socially acceptable.*

## SECTION 6. REPORTING EPIDEMIOLOGICAL STUDIES

(1) Principal investigators shall submit progress reports to the ethics review committee through the institute head, as specified in the approved research proposal for a study period extending for several years.

*(Provision)*

*Research proposals should include deadlines for submission of progress reports, which shall be subject to approval by the ethics review committee. The benchmark time period should be every three years.*

(2) Principal investigators shall immediately report any adverse events to study subjects that may arise to the ethics review committee, through the institute head.

(3) Ethics review committee shall provide a statement on alteration or termination of the research proposals and other issues on epidemiological studies when principal investigators submit or present progress reports, pursuant to parts (1) and (2).

(4) When deciding alteration or termination of the research proposals and other epidemiological issues, the institute head should respect the opinion of the ethics review committee.

(5) Principal investigators shall modify research proposals or terminate studies when so stipulated by the institute head or the ethics review committee.

(6) Principal investigators shall report a summary of research findings to the ethics review committee through the research institute head immediately upon conclusion of epidemiological

study.

*(Provision)*
*Researchers not belonging to a research institute are required to report to the ethics review committee from which they seek evaluation, pursuant to sections (1), (2) and (6).*

# CHAPTER 3. INFORMED CONSENT

## SECTION 7. PROCEDURES FOR OBTAINING INFORMED CONSENT

Ordinarily, informed consent should be obtained from research subjects according to the following rules.

Where it is infeasible to observe these rules due to such reasons as methodology or purpose of the research, nature of research subjects, or the like, exceptions to the Guidelines may be permitted only when approval of both the ethics review committee and the institute head have been secured. In such cases, these general rules may be relaxed, excused, or replaced by another appropriate procedure for obtaining informed consent, as the case may be.

*(Provisions)*

*Ethics review committees shall make certain that all of the following conditions are met in research proposals, whenever relaxing, waiving or deviating from the general rules for obtaining informed consent:*

*1- The epidemiological research involves no more than minimal risk to the subjects;*

*2- The relaxation, waiver or deviation will not adversely affect the interests of the subjects;*

*3- The epidemiological research could not practically be carried out without the relaxation, waiver or deviation;*

*4- Whenever appropriate, any of the following measures*