今般のヘルシンキ宣言改訂について
the 75th WMA General Assembly, Helsinki, Finland, October 2024

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※本報告は、基本的に演者側による仮訳をふまえたものとなります。

九州大学

ヘルシンキ宣言　改訂の経緯

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964
and amended by the:

29th WMA General Assembly, Tokyo, Japan, October 1975
35th WMA General Assembly, Venice, Italy, October 1983
41st WMA General Assembly, Hong Kong, September 1989
48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996
52nd WMA General Assembly, Edinburgh, Scotland, October 2000
53rd WMA General Assembly, Washington DC, USA, October 2002 (Note of Clarification added)
55th WMA General Assembly, Tokyo, Japan, October 2004 (Note of Clarification added)
59th WMA General Assembly, Seoul, Republic of Korea, October 2008
64th WMA General Assembly, Fortaleza, Brazil, October 2013

and by the 75th WMA General Assembly, Helsinki, Finland, October 2024

各項の新旧対照

今回の改訂（ヘルシンキ改訂）**The 75th WMA General Assembly, Helsinki, Finland, October 2024**

前回の改訂（フォルタレザ改訂） **The 64th WMA General Assembly, Fortaleza, Brazil, October 2013**

PREAMBLE （序文）

1. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human participants, including research using identifiable human material or data.

1. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.

☞個人の権利・主体性を尊重するため「被験者(研究対象者)」から「研究参加者」の表記に置き換える。

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2. While the Declaration is adopted by physicians, the WMA holds that these principles should be upheld by all individuals, teams, and organizations involved in medical research, as these principles are fundamental to respect for and protection of all research participants, including both patients and healthy volunteers.

2. Consistent with the mandate of the WMA, the Declaration is addressed primarily to physicians. The WMA encourages others who are involved in medical research involving human subjects to adopt these principles.

☞「人を対象とする医学研究に関与する医師以外の人々に対してもこれらの原則が採り入れられることを推奨」から「医学研究に関わるすべての個人、チーム、組織によって支持されるべき」旨に修正。
併せて、研究参加者には患者と健康なボランティアが含まれることを明示。

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GENERAL PRINCIPLES （一般原則）

5. Medical progress is based on research that ultimately must include participants.
Even well-proven interventions should be evaluated continually through research for their safety, effectiveness, efficiency, accessibility, and quality.

5. Medical progress is based on research that ultimately must include studies involving human subjects.

6. The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Even the best proven interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.

☞「医学研究は最終的に参加者を含むものでなければならない」ことに加えて、従前の第6項「十分に証明された介入であってもその安全性、有効性、効率性、アクセシビリティ、質について、研究を通じて継続的に評価されるべきである」旨を第5項に含めるかたちで追記。

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GENERAL PRINCIPLES （一般原則）

6. Medical research involving human participants is subject to ethical standards that promote and ensure respect for all participants and protect their health and rights.

Since medical research takes place in the context of various structural inequities, researchers should carefully consider how the benefits, risks, and burdens are distributed.

Meaningful engagement with potential and enrolled participants and their communities should occur before, during, and following medical research. Researchers should enable potential and enrolled participants and their communities to share their priorities and values; to participate in research design, implementation, and other relevant activities; and to engage in understanding and disseminating results.

7. Medical research is subject to ethical standards that promote and ensure respect for all human subjects and protect their health and rights.

以下について追記。

・「研究者は、研究によってもたらされる利益、リスク、負担がどのようになるか（どのように配分されることになるか）注意深く検討」すべきこと、そして「医学研究の実施前から実施後に至るまで、研究参加者やそのコミュニティと、有意義な関わりをもつべき」ことに言及。

・「研究参加者やそのコミュニティ（登録された参加者のみならず潜在的な参加者を含む。）が、研究計画の策定、研究の実施などに参加したり、研究の結果を理解してその普及に関わったりすることで、彼らにとって重要な事柄、価値観を共有できるようにするべき」こと。

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GENERAL PRINCIPLES （一般原則）

7. The primary purpose of medical research involving human participants is to generate knowledge to understand the causes, development and effects of diseases; improve preventive, diagnostic and therapeutic interventions; and ultimately to advance individual and public health.

These purposes can never take precedence over the rights and interests of individual research participants.

6. The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments).

（以下については第5項に編入）
Even the best proven interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.

8. While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.

これまでの第6項及び第８項から再編。
「医学研究の主たる目的が、疾患の原因、発症、影響を理解するための知識を生み出し、予防、診断、治療介入を向上させること、ひいては、個人および公衆の健康を増進させること」を明示。
　これまで第8項にあった「個々の研究参加者の権利や利益に優先されることは決してない」旨を末尾に追記。

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GENERAL PRINCIPLES （一般原則）

（新設）

8. While new knowledge and interventions may be urgently needed during public health emergencies, it remains essential to uphold the ethical principles in this Declaration during such emergencies.

（記載なし）

☞公衆衛生上の緊急事態についての文言を新設。

「公衆衛生上の緊急事態においては、新たな知識や介入が緊急に必要とされるかもしれないが、そのような緊急事態においても、本宣言の倫理原則を守ることが不可欠であることに変わりはない」旨を明示。

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GENERAL PRINCIPLES （一般原則）

12. Medical research involving human participants must be conducted only by individuals with the appropriate ethics and scientific education, training and qualifications. Such research requires the supervision of a competent and appropriately qualified physician or other researcher.

Scientific integrity is essential in the conduct of medical research involving human participants. Involved individuals, teams, and organizations must never engage in research misconduct.

12. Medical research involving human subjects must be conducted only by individuals with the appropriate ethics and scientific education, training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional.

☞「医師あるいはその他の医療専門職（other health care professional）」から「医師あるいはその他の研究者（other researcher）」に表現を変更。

☞研究不正に係る文言（「科学的なインテグリティ（公正性、誠実さ）は、医学研究を実施するうえで不可欠であり、研究に関わる個人、チーム、組織は、決して研究不正を行ってはならない」旨）を末尾に追記。

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Individual, Group, and Community Vulnerability（個人、集団、コミュニティの脆弱性）

19. Some individuals, groups, and communities are in a situation of more vulnerability as research participants due to factors that may be fixed or contextual and dynamic, and thus are at greater risk of being wronged or incurring harm.
When such individuals, groups, and communities have distinctive health needs, their exclusion from medical research can potentially perpetuate or exacerbate their disparities.
Therefore, the harms of exclusion must be considered and weighed against the harms of inclusion.
In order to be fairly and responsibly included in research, they should receive specifically considered support and protections.

19. Some groups and individuals are particularly vulnerable and may have an increased likelihood of being wronged or of incurring additional harm.

All vulnerable groups and individuals should receive specifically considered protection.

☞「様々な要因で、研究参加者として脆弱な状況に置かれ、不当な扱いを受けたり、危害を被ったりするリスクが増大する個人・集団・コミュニティがある」ことを示したうえで、「そのような個人・集団・コミュニティに特有の健康上のニーズがある場合、彼らが医学研究から排除されることになれば、格差を永続させたり、悪化させたりするおそれがある」ことに言及。

☞「したがって、研究から排除されることによる害が考慮され、研究に組み入れられることによる害と比較衡量されなければならない」こと、そして、「公正かつ責任のある研究への参加のため、彼らは特別な配慮によるサポートと保護を受けるべき」ことを明示。

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Individual, Group, and Community Vulnerability（個人、集団、コミュニティの脆弱性）

20. Medical research with individuals, groups, or communities in situations of particular vulnerability is only justified if it is responsive to their health needs and priorities and the individual, group, or community stands to benefit from the resulting knowledge, practices, or interventions.
Researchers should only include those in situations of particular vulnerability when the research cannot be carried out in a less vulnerable group or community, or when excluding them would perpetuate or exacerbate their disparities.

20. Medical research with a vulnerable group is only justified if the research is responsive to the health needs or priorities of this group and the research cannot be carried out in a non-vulnerable group. In addition, this group should stand to benefit from the knowledge, practices or interventions that result from the research.

☞「研究者は、脆弱な立場にある集団・コミュニティでなければ研究を実施できない場合、あるいは、彼らを研究から除外することでもたらされる格差が永続化または悪化するような場合にのみ、特定の脆弱な状況にある人々を含めるべき」旨を明示。

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Scientific Requirements and Research Protocols（科学的要件と研究計画書）

21. Medical research involving human participants must have a scientifically sound and rigorous design and execution that are likely to produce reliable, valid, and valuable knowledge and avoid research waste.
The research must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and, as appropriate, animal experimentation. The welfare of animals used for research must be respected.

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21. Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and, as appropriate, animal experimentation. The welfare of animals used for research must be respected.

☞医学研究について「信頼性があり、妥当であり、価値のある知識を生み出し、研究の無駄を省くことができるような、科学的に健全で、厳格な計画と実施を伴うもの」でなければならない旨を示す。

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Research Ethics Committees（倫理審査委員会）

23. The protocol must be submitted for consideration, comment, guidance, and approval to the concerned research ethics committee before the research begins. This committee must be transparent in its functioning and must have the independence and authority to resist undue influence from the researcher, the sponsor, or others.

The committee must have sufficient resources to fulfill its duties, and its members and staff must collectively have adequate education, training, qualifications, and diversity to effectively evaluate each type of research it reviews.

The committee must have sufficient familiarity with local circumstances and context, and include at least one member of the general public. It must take into consideration the ethical, legal, and regulatory norms and standards of the country or countries in which the research is to be performed as well as applicable international norms and standards, but these must not be allowed to reduce or eliminate any of the protections for research participants set forth in this Declaration.

When collaborative research is performed internationally, the research protocol must be approved by research ethics committees in both the sponsoring and host countries.

The committee must have the right to monitor, recommend changes to, withdraw approval for, and suspend ongoing research. Where monitoring is required, the researcher must provide information to the committee and/or competent data and safety monitoring entity, especially about any serious adverse events. No amendment to the protocol may be made without consideration and approval by the committee. After the end of the research, the researchers must submit a final report to the committee containing a summary of the findings and conclusions.

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23. The research protocol must be submitted for consideration, comment, guidance and approval to the concerned research ethics committee before the study begins. This committee must be transparent in its functioning, must be independent of the researcher, the sponsor and any other undue influence and must be duly qualified.

It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration.

The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No amendment to the protocol may be made without consideration and approval by the committee. After the end of the study, the researchers must submit a final report to the committee containing a summary of the study's findings and conclusions.

☞倫理審査委員会の透明性、独立性の他、不当な影響に抗しうる権限についても言及された。

☞倫理審査委員会の委員及びスタッフは、様々な態様の研究を効率的に審査するために、「十分な教育、訓練、資格、多様性を備えていなければならない」旨が明示された。
　また、「ローカルな状況等に十分精通していること、少なくとも1名の一般市民を含まなければならないこと」など加筆。

☞国際共同研究では、スポンサー国（研究を計画・運営する側）とホスト国（研究を実施する側）の双方の倫理審査委員会から研究計画の承認を得なければならない旨が追記された。

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Free and Informed Consent（自由意思に基づく同意）

28. In medical research involving human participants incapable of giving free and informed consent, the physician or other qualified individual must seek informed consent from the legally authorized representative, considering preferences and values expressed by the potential participant.

Those persons incapable of giving free and informed consent are in situations of particular vulnerability and are entitled to the corresponding safeguards. In addition to receiving the protections for the particularly vulnerable, those incapable of giving consent must only be included if the research is likely to either personally benefit them or if it entails only minimal risk and minimal burden.

28. For a potential research subject who is incapable of giving informed consent, the physician must seek informed consent from the legally authorised representative.

These individuals must not be included in a research study that has no likelihood of benefit for them unless it is intended to promote the health of the group represented by the potential subject, the research cannot instead be performed with persons capable of providing informed consent, and the research entails only minimal risk and minimal burden.

29. When a potential research participant who is incapable of giving free and informed consent is able to give assent to decisions about participation in research, the physician or other qualified individual must seek that assent in addition to the consent of the legally authorized representative, considering any preferences and values expressed by the potential participant. The potential participant's dissent should be respected.

29. When a potential research subject who is deemed incapable of giving informed consent is able to give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorised representative. The potential subject's dissent should be respected.

☞医師等は、法定代理人の同意に加えて参加者候補にアセントを求める場合に「彼らが表明する選好・価値観等を考慮しなければならない」旨が追記された。

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Free and Informed Consent（自由意思に基づく同意）

32. Physicians or other qualified individuals must obtain free and informed consent from research participants for the collection, processing, storage, and foreseeable secondary use of biological material and identifiable or re-identifiable data.

Any collection and storage of data or biological material from research participants for multiple and indefinite uses should be consistent with requirements set forth in the WMA Declaration of Taipei, including the rights of individuals and the principles of governance.
A research ethics committee must approve the establishment and monitor ongoing use of such databases and biobanks.

Where consent is impossible or impracticable to obtain, secondary research on stored data or biological material may be done only after consideration and approval of a research ethics committee.

32. For medical research using identifiable human material or data, such as research on material or data contained in biobanks or similar repositories, physicians must seek informed consent for its collection, storage and/or reuse. There may be exceptional situations where consent would be impossible or impracticable to obtain for such research.

In such situations the research may be done only after consideration and approval of a research ethics committee.

☞試料やデータ（特定の個人が識別・再識別可能なデータを含む。）の収集・処理・保管の他、「予測可能な二次利用」については、研究参加者から自由意思に基づくインフォームド・コンセント」を得ることを前提とした表記となった。

☞「多目的・無期限での用途のために研究参加者から試料やデータを収集・保管するにあたっては、世界医師会の「台北宣言」に定められた要件に合致するものでなければならない」旨の明示。
「倫理審査委員会はこのようなデータベースやバイオバンクの設立を承認し、当該利用を継続的に監視しなければならない」旨も追記された。

※「台北宣言」…2016年、WMA（世界医師会）が初版（2002年）の改訂版として、台北で開催された第67回世界医師会総会で採択した「ヘルスデータベースとバイオバンクに関する倫理的検討に関する宣言」。データや試料の二次利用等について規定。個人の権利やガバナンスの原則を含む。この台北宣言の原則と、ヘルシンキ宣言を連結させることで、研究参加者の保護を確保しつつ、データ駆動型の研究を促進することが期待される。

参照：栗原千絵子，松山琴音「翻訳 『ヘルシンキ宣言』と『台北宣言』を繋ぐ：未来を志向する研究倫理の重要課題」、臨床評価50（1）2022，49-57

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Post-Trial Provisions（試験終了後の対応）

34. In advance of a clinical trial, post-trial provisions must be arranged by sponsors and researchers to be provided by themselves, healthcare systems, or governments for all participants who still need an intervention identified as beneficial and reasonably safe in the trial. Exceptions to this requirement must be approved by a research ethics committee.

Specific information about post-trial provisions must be disclosed to participants as part of informed consent.

34. In advance of a clinical trial, sponsors, researchers and host country governments should make provisions for post-trial access for all participants who still need an intervention identified as beneficial in the trial.

This information must also be disclosed to participants during the informed consent process.

☞「臨床試験に先立って、当該試験で有益かつ安全であることが合理的に確認された介入を必要とする参加者のため、スポンサー・研究者、あるいは、政府等によって、試験終了後の対応に係る調整がなされなければならない」旨とともに、研究参加者へのインフォームド・コンセントに含める旨を示す。
　なお「例外的な対応（この要件を適用しない場合）については、倫理審査委員会の承認を得なければならない」旨を明示。

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Unproven Interventions in Clinical Practice（臨床における未実証の介入）

37. When an unproven intervention is utilized in an attempt to restore health or alleviate suffering for an individual patient because approved options are inadequate or ineffective and enrollment in a clinical trial is not possible, it should subsequently be made the object of research designed to evaluate safety and efficacy.

Physicians participating in such interventions must first seek expert advice, weigh possible risks, burdens, and benefits, and obtain informed consent.
They must also record and share data when appropriate and avoid compromising clinical trials.

These interventions must never be undertaken to circumvent the protections for research participants set forth in this Declaration.

37. In the treatment of an individual patient, where proven interventions do not exist or other known interventions have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorised representative, may use an unproven intervention if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering.

This intervention should subsequently be made the object of research, designed to evaluate its safety and efficacy.

In all cases, new information must be recorded and, where appropriate, made publicly available

☞未実証の介入が試みられるにあたって、承認された選択肢が不十分であったり効果がない場合の他「臨床試験への登録が不可能である場合」の文言が追記されたうえで、「その後、安全性と有効性を評価するための研究の対象とすべき」とされた。
　なお、「記録をとってデータの共有化をはかることで、臨床試験に支障がおきないようにしなければならない」旨も示された。

☞まずは専門家の助言を求め、そして「起こりうるリスク、負担、利益を比較検討」したうえで、インフォームド・コンセントを得なければならない旨の記載となった。

☞こうした臨床上の未実証の介入は、このヘルシンキ宣言の「研究参加者の保護」に関する規定を回避するために行われてはならない旨が末尾にあらためて追記された。

まとめ　今回の改訂（2024年ヘルシンキ改訂）のポイント

■全体的に従前の「被験者 (human subject)」から「参加者 (human participant)」に置き換えられた。
併せて、研究参加者とコミュニティの関与について強調。
研究者側と、患者、健常者、潜在的な参加者（将来の参加者）との関係性をいっそう意識した記載にあらためられた。

■研究計画の策定・実施・終了後に至るまで研究参加者との関係のあり方に着眼。
研究参加者の価値観等にも配慮するべきことに言及された。

■医学研究に携わる個人だけではなく、チームや組織など。より広範な支持に基づくことの重要性を強調。
医師に加えて「その他の研究者」といった用語も登場し、医師以外の職種との共同研究にも留意される記載となった。

■医学研究の主たる目的の中に、個人および公衆の健康を増進させることも盛り込まれた。
また、公衆衛生上の緊急状況においても、この宣言の基本的な理念を遵守することの重要性が挙げられた。

■脆弱な立場にある方々を対象とする研究を実施するにあたっては、そうした人たちの参加がなければ研究ができない場合の他、「そうした人たちを研究から除外することでもたらされる格差が永続化または悪化するような場合」も、特定の脆弱な状況にある人たちを含めるべきことが示された。

■科学的要件に係る規定において、研究不正に係る文言も追記。

■倫理審査委員会の委員及びスタッフの要件について追記。国際共同研究における対応についても言及。

■研究で用いられる試料・情報の二次利用等について、台北宣言もふまえたかたちで文言が追記された。

■最後の「臨床における未実証の介入」については、診療だけではなく、研究との関係性についてもいっそう意識した記載ぶりにあらためられた。