IJCOM 2025 July;5(1):31-5

Informed Consent in Occupational Health Research: A Review on Ethical Challenges

Andrias Norris

Occupational Medicine Magister Program, Department of Community Medicine, Faculty of Medicine, Universitas Indonesia, Jakarta, Indonesia

*Corresponding Author: Andrias Norris
Email: *andrias.norris1986@gmail.com*

Abstract

Background: In research involving human subjects, including occupational health research, informed consent must be obtained from prospective participants. However, the extent to which informed consent should be obtained, what should be disclosed to participants, and how the process should be conducted are not always given due consideration in research.
Methods: In April 2025, we conducted a journal search using basic techniques across all sources on Google, Google Scholar and Scopus. We also searched PubMed using advanced search techniques and medical terms (MeSH terms). The journals were published in English at any time between 2014 and 2025.
Results: In a study involving human subjects, ethical principles must be followed. One of these principles is obtaining informed consent from potential participants. No one, including the state, can force someone to participate in research, and participants can withdraw from the study at any time. Researchers must obtain informed consent from potential participants. The principle of informed consent requires information, understanding and voluntariness to be fully upheld, ensuring that participants are fully aware of the research being conducted and thereby ensuring the validity of the research results. In certain cases, informed consent may be modified or waived with the approval of the research ethics committee.
Conclusions: Researchers can learn about the important role of informed consent in research involving human participants, including those involved in occupational health studies. If prospective participants do not understand the informed consent process, this can cause research to become biased or even lead to withdrawal from the research process. In addition to complying with the three principles of informed consent (information, understanding and voluntariness), the consent process must also take into account the appropriate format, which should be concise and focused.
Keywords: informed consent, health research, workplace, ethical reasons, occupational

Abstrak

***Pendahuluan**: Dalam sebuah penelitian yang melibatkan manusia, termasuk penelitian kesehatan kerja, informed consent harus dilakukan kepada calon subjek atau partisipan. Akan tetapi, sejauh mana informed consent harus dilakukan, apa yang harus diungkapkan kepada calon patirtisipan, serta bagaimana proses persetujuan informed consent yang terkadang tidak dianggap serius dalam suatu penelitian atau sekadarnya.*
***Metode**: Pada bulan April 2025, kami melakukan teknik pencarian jurnal di semua sumber di Google, Google Scholar, dan Scopus. Kami mencari di PubMed menggunakan teknik pencarian lanjutan dengan istilah medis (istilah MeSH). Jurnal-jurnal tersebut diterbitkan dalam bahasa Inggris kapan saja mulai dari tahun 2014 hingga dan termasuk tahun 2025.*
***Hasil**: Pada sebuah penelitian yang melibatkan manusia harus melaksanakan kaidah-kaidah etis, salah satunya melakukan informed consent kepada calon partisipan. Siapapun tidak bisa melakukan pemaksaan seseorang untuk berpartisipasi dalam penelitian termasuk negara dan partisipan pun bisa keluar dari penelitian kapanpun yang diinginkan. Peneliti harus melakukan informed consent kepada calon partisipan. Prinsip informed consent yakni Informasi, pemahaman dan kesukarelaan harus betul-betul dijalankan agar partisipan menjadi paham akan penelitian yang dilakukan sehingga hasil penelitian menjadi valid. Ada kasus-kasus tertentu informed consent bisa dimodifikasi atau dikesampingkan apabila disetujui oleh komite etik penelitian.*
***Kesimpulan**: Peneliti dapat mempelajari tentang peran penting informed consent dalam sebuah penelitian yang melibatkan manusia termasuk pada penelitian kesehatan kerja. Informed consent yang tidak dipahami calon partisipan dapat menyebabkan penelitian menjadi bias atau bahkan menarik diri dari proses penelitian. Pemberian informed consent kepada calon partisipan selain harus sesuai dengan kaidah (Informasi, Pemahaman dan Kesukarelaan) juga harus memperhatikan format yang tepat, ringkas dan terfokus.*
***Kata kunci**: informed consent, penelitian kesehatan, tempat kerja, ethical reasons occupational*

Background

In occupational health research, which inevitably involves human participants/subjects, informed consent is necessary for the results to be accepted as ethical and valid, and for them to be used safely and effectively for human health.[1,6] Informed consent protects the rights of participants, ensuring that they are not harmed by any intentional or unintentional abuse by researchers. Informed consent is also important in order to avoid research bias due to participants not understanding the purpose and objectives of the research, or their own role in it.[5]

The concept of informed consent originated from a series of four court decisions in the early 20th century that established the principle of patient autonomy in the United States. The first guidelines for principles such as informed consent were implemented in Germany in the early 1900s and in 1931. However, these guidelines were violated and Nazi crimes against humanity continued.[7]

Following the trial of Nazi German doctors for war crimes involving experiments that disregarded human dignity, resulting in the disability and death of hundreds of thousands of prisoners, the Nuremberg Code of 1947 was established. The Nuremberg Code outlines three important principles regarding research ethics in healthcare: (1) protecting the integrity of research subjects, (2) establishing ethical requirements for conducting healthcare research involving human subjects, and (3) informed consent.[1]

Informed consent with participants is sometimes viewed as a mere formality, meaning it does not become a focal point for researchers in a study.[3] However, informed consent is an essential component of initiating a study, particularly with regard to research ethics and valid research outcomes. Conversely, researchers who focus on creating informed consent may be unsure about how to implement it. They may wonder whether their informed consent meets ethical standards, whether participants can understand it, what information must be disclosed and what should be omitted, and whether it is practical to implement. Research is often driven by limited time and the need to recruit participants who meet the study's requirements in terms of both quantity and quality. Therefore, the informed consent document must be understandable to potential participants, who must then be able to give their voluntary agreement to participate in the research.[4,8,9]

Methods

We conduct literature yang berkaitan dengan informed consent pada dan permasalahannya yang dilakukan pada bulan Maret-April 2025. Dalam pencarian We consulted Three databases, yakni Google Scholar, Scopus dan PubMed dengan metode basic search for key terms "Informed Consent", "Informed Consent in Health Reasearch", "Informed Concent in the workplace", "ethical reason for obtaining Informed Consent in Occupational health Research".

In this study, we excluded literature sources from magazines and articles from the internet, including grey literature. We included sources published in English from 2014 to 2025.

Results

After conducting a search, we found 12 pieces of literature, consisting of 11 journal articles and one regulatory e-book, which discussed informed consent in health research. Of these, only two specifically discussed informed consent in workplace research.

Almost all of the literature explains the history of informed consent and the importance of its implementation in scientific health research involving human participants. However, in line with the aforementioned issue of how to implement informed consent in a way that is both understandable and effective for participants, this topic was discussed in each of the following journals, which are listed alphabetically:

Discusion

Any research involving human subjects must adhere to ethical principles. One of these principles is obtaining informed consent from potential participants.[1,2] No one, including the state, can force someone to participate in research, and participants can withdraw at any time. Researchers must obtain informed consent from potential participants.[3] The three principles of informed consent — information, understanding and voluntariness — must be strictly adhered to in order to ensure that participants fully comprehend the research being conducted and thereby ensure the validity of the research results.[3–5] Informed consent often becomes invalid due to participants' lack of understanding of

Table 1. List of 12 pieces literatures, sorted alphabetically.

Title	Author	Year	Study Design	Key Finding
(Why) should we require consent to participation in research?	Wertheimer, Alan	2014	Analytical-conseptual	Neither the state nor anyone else can force participants to take part in research. They must go through an informed consent process based on the principles of information, understanding, and voluntariness. Participants must also be informed about the purpose of the research, as well as the risks and benefits of participating..
A modern history of informed consent and the role of key information	Bazzano et al	2021	Literature Review	The key information in the informed consent document should be concise and presented at the beginning. This information should also be written in a way that is easy to understand.
Dynamic-informed consent: a potential solution for ethical dilemmas in population sequencing initiatives	Dankar et al	2020	Literaure Review	In the context of genomic research, informed consent allows researchers to provide ongoing information and request renewed consent throughout a study, rather than just obtaining general consent at the outset. One major challenge that still needs to be addressed is ensuring participants understand the research, as some studies do not review this.
Ethical aspects in occupational health research: a narrative review of the literature	Yanez and Reynaldos	2025	Literature Review	Ezekiel Emanuel's seven basic principles of occupational health research are: 1) Social value 2) Scientific validity 3) Fair selection of subjects 4) Favourable risk-benefit ratio 5) Objective and non-discriminatory research 6) Independent research 7) Transparent and non-discriminatory research
Four reasons why too many informed consents to clinical research are invalid: a critical analysis of current practices	Wisgalla A and Hasford	2022	Analytical-conseptual	In order for the results to be valid, the information in the informed consent form must be easy for participants to understand. Therefore, the following should be avoided: • Long document narratives (no more than 1,250 words or 2–3 pages). • Low readability of the informed consent document, e.g. due to poor font choice or layout, can make it difficult for participants to understand the document. • Therapeutic misconception: some participants believe that participating in a clinical trial is their only treatment option, even though other treatments are available if they do not participate. In other situations, participants fail to recognise that the clinical trial is research and not routine care. • The potential benefits of trial participation are not sufficiently addressed. Side effects are often discussed in excessive detail, while the benefits of the research are discussed too briefly. There are only limited guidelines on this matter.

Title	Author	Year	Study Design	Key Finding
Informed Consent in Mental Health Research at Workplace	Beby and Basrowi	2024	Literature Review	Informed consent must be obtained for all research involving human participants, including mental health research. Participants must be made aware that their participation is voluntary and that they should not fear stigmatisation or discrimination as a result of taking part in the research.
Informed Consent in the Workplace Nutrition Intervention Studies: A Narrative Review on Ethical Challenges	Narendraputra and Basrowi	2024	Literature Review	In an informed consent, participants must be informed of the nature of the intervention, its potential risks and benefits, and their right to withdraw from the study at any time.
Informed Consent: What Must Be Disclosed and What Must Be Understood?	Millum and Bromwich	2021	Analytical-conseptual	When obtaining informed consent, researchers must not withhold important information from participants, such as details about the purpose of the research or potential side effects. Even if participants understand the contents of the informed consent document, it is invalid and void.
Participants' understanding of informed consent in clinical trials over three decades: systematic review and meta-analysis	Tam N et al	2015	Literature Review	Three-quarters of participants did not understand the nature of the research, their right to refuse or withdraw from participation, or the direct benefits of the research for participants.
Pedoman dan Standar Etik Penelitian dan Pengembangan Kesehatan Nasional	Komite Etik Penelitian dan Pengembangan Kesehatan Nasional	2021	Pedoman (regulasi)	The Informed Consent Form has been issued by the National Health Research and Development Ethics Committee, and compliance with it is required
Researchers' views on, and experiences with, the requirement to obtain informed consent in research involving human participants: a qualitative study	Xu A et al	2020	Semi Structed Interviewes	The open relationship between researchers and participants enables participants to make informed decisions regarding informed consent.
When is it impractical to ask informed consent? A systematic review	Laurijssen et al	2022	Sistematic review and Metaanalysis	Informed consent may be modified or waived if the research ethics committee deems it impractical and of minimal risk and social value. However, impracticality remains a matter of debate, as it may be impractical for researchers due to the large number of participants, participants who cannot be reached, or a lack of necessary resources.

the research. In creating informed consent for health research, researchers must follow the informed consent format guidelines issued by the National Health Research and Development Ethics Committee. They should also use clear, understandable language and avoid jargon (maximum 2–3 pages and no more than 1.250 words).[1,7,9]

When disclosing information in the informed consent document, researchers must be transparent with participants and must not withhold information that should be provided, such as details of the potential side effects of clinical trials or research.[2,4] In certain studies, dynamic informed consent has also been implemented, meaning that informed consent is obtained not only at the beginning of the study, but also throughout if deemed necessary, requiring renewed consent from participants.[10] Providing complete information greatly assists participants in gaining a full understanding of the research and in making decisions about whether to participate.[4,11] In certain cases, for reasons of impracticality, minimal risk and social value, informed consent may be waived or modified after approval has been obtained from the research ethics committee.[12]

Conclusion

Researchers can learn about the important role of informed consent in research involving human participants, including those involved in occupational health studies. If prospective participants do not understand the informed consent process, this can cause research to become biased or even lead to withdrawal from the research process. In addition to complying with the three principles of informed consent (information, understanding and voluntariness), the format must be concise and focused.

References

1. Komite Etik Penelitian dan Pengembangan Kesehatan Nasional. Pedoman dan standar etik penelitian dan pengembangan kesehatan nasional [Internet]. 1st ed. Jakarta: Lembaga Penerbit Balitbangkes; 2021. Available from: https://repository.badankebijakan.kemkes.go.id/id/eprint/4214/1/Pedoman%20dan%20Standar%20Etik%20Penelitian%20dan%20Pengembangan%20Kesehatan%20Nasional.pdf
2. Beby Etika Sari Yudiarti, Basrowi RW. Informed consent in mental health research at workplace. The Indonesian Journal of Community and Occupational Medicine [Internet]. 2024;4:36–44. Doi.org/10.53773/ijcom.v4i1.135.36-44
3. Wertheimer A. (Why) should we require consent to participation in research? J Law Biosci [Internet]. 2014 ;1:137–82. Doi:10.1093/jlb/lsu008
4. Millum J, Bromwich D. Informed consent: What must be disclosed and what must be understood? Am J Bioethics 2021;21:46–58.
5. Tam NT, Huy NT, Thoa LTB, Long NP, Trang NTH, Hirayama K, et al. Participants' understanding of informed consent in clinical trials over three decades: systematic review and meta-analysis. Bull World Health Organ [Internet]. 2015;93:186-198H. Doi: http://dx.doi.org/10.2471/BLT.14.141390
6. Yáñez-Flores K, Reynaldos-Grandón K. Ethical aspects in occupational health research: A narrative review of the literature. Salud, Ciencia y Tecnología [Internet]. 2025;5:967. Doi: 10.56294/saludcyt2025967
7. Wisgalla A, Hasford J. Four reasons why too many informed consents to clinical research are invalid: a critical analysis of current practices. BMJ Open [Internet]. 2022;12:e050543. Available from: https://www.proquest.com/docview/3117719439/fulltextPDF?parentSessionId=tzDNv0gVf3C8pgRt7C4asDvrUWOQ9FSmPK%2BlnbBf5vs%3D&pq-origsite=summon&accountid=17242&sourcetype=Scholarly%20Journals
8. Hutton JL, Eccles MP, Grimshaw JM. Ethical issues in implementation research: a discussion of the problems in achieving informed consent. Implementation Science [Internet]. 2008;3:52. Available from: https://link.springer.com/article/10.1186/1748-5908-3-52
9. Narendraputra A, Basrowi R. Informed consent in the workplace nutrition intervention studies: A narrative review on ethical challenges. JISN 2024;1:37–45.
10. Dankar FK, Gergely M, Malin B, Badji R, Dankar SK, Shuaib K. Dynamic-informed consent: A potential solution for ethical dilemmas in population sequencing initiatives. Comput Struct Biotechnol J [Internet]. 2020 [cited 2025 Apr 26];18:913–21.
11. Xu A, Baysari MT, Stocker SL, Leow LJ, Day RO, Carland JE. Researchers' views on, and experiences with, the requirement to obtain informed consent in research involving human participants: a qualitative study. BMC Med Ethics [Internet] 2020;21:93. Doi.org/10.1186/s12910-020-00538-7
12. Laurijssen SJ, van der Graaf R, van Dijk WB, Schuit E, Groenwold RH, Grobbee DE, et al. When is it impractical to ask informed consent? A systematic review. Clinical Trials [Internet]. 2022;19:545–60. Doi: 10.1177/17407745221103567. Epub 2022 Jul 1
13. Bazzano LA, Durant J, Brantley PR. A Modern History of Informed Consent and the Role of Key Information. Ochsner J 2021 Spring;21(1):81-85. Doi: 10.31486/toj.19.0105