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Methods to obtain informed consent in medical and biological research involving human subject: application to studies on digestive endoscopy

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Authors
Noriya Uedo[1], Thierry Ponchon[2]

Institutions
1 Department of Gastrointestinal Oncology, Osaka International Cancer Institute, Osaka, Japan
2 Digestive Diseases Department, Lyon University Hospital, France.

Bibliography
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Corresponding author
Noriya Uedo, Department of Gastrointestinal Oncology, Osaka International Cancer Institute, 3-1-69 Otemae, Chuo-ku, Osaka 541-8567, Japan
Fax: +81-6-6945-1900
noriya.uedo@gmail.com

The Declaration of Helsinki states that participation by individuals in medical research as subjects is voluntary, and consent must be obtained after adequate provision of information about the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study [1]. Moreover, the potential subject must be informed of the right to refuse study participation or to withdraw consent at any time without reprisal. For medical research using identifiable human material or data, physicians must seek informed consent for its collection and/or reuse. However, in exceptional situations in which consent would be impossible or impractical to obtain, such as retrospective studies using old existing materials, the research may be done only after approval by a research ethics committee.

In the randomized controlled trial by Ikeda et al., informed consent was obtained by an opt-out method [2]. The protocol for this study was approved on December 20, 2018 by the hospital Ethics Committee, so the Ethical Guidelines for Medical and Health Research Involving Human Subjects in Japan issued in 2014 [3] applied to this study. According to the Japanese guideline, obtaining informed consent is based on invasiveness of medical practice in the study, study design, and use of biospecimens. In the case of an observational study involving a non-invasive medical practice using non-biospecimen (i. e., medical data), informed consent can be obtained with an opt-out method, otherwise opt-in informed consent is necessary. Of course, informed consent for retrospective studies can be obtained with an opt-out method or even be waived for studies using anonymized existing medical material or data. In this regard, this study did not comply with the guideline. However, we were aware that the content of this study was important for endoscopic practice around the world, and recognized that approval by the hospital ethics committee (H30–51) was prioritized. Accordingly, we made the decision to accept this manuscript.

We receive many manuscripts about clinical studies in digestive endoscopy for publication in Endoscopy International Open. Although almost all of them indicate that these studies were conducted in accordance with the Declaration of Helsinki, whether a study is truly prospective or retrospective and informed consent was adequately obtained or not often is unclear. The authors commonly describe studies as having used a prospective database. Although the data were prospectively input, studies that use existing data should be clearly described as retrospective. Data for a prospective study are collected after initiation of the study. Given this, information about a prospective study should be entered in a clinical study registry, and the dates of Ethics Committee approval, study registration, and the beginning and the end of the study should be documented in the manuscript. Whether informed consent was obtained specifically for study participation or for sole performance of an endoscopic procedure is unclear in some manu-

scripts. If a study was truly prospective, informed consent needs to be obtained for study participation after the above-mentioned items are described to potential participants. In most countries, informed consent for retrospective studies using anonymized existing data is abjured; therefore, it may be described as it was, and only Ethics Committee approval is stated in the main text. An unclear description of details such as these makes it difficult for individual readers to assess the level of evidence represented by a clinical study and if such a study is included in systematic reviews that are part of guidelines, it could eventually result in confusion about the body of scientific knowledge.

Competing interests

Honoraria for lectures: Olympus Co Ltd, FUJIFILM Co Ltd, Boston Scientific Japan, Daiichi-Sankyo Co Ltd, Takeda Pharmaceutical Co Ltd, EA Pharma Co Ltd, Otsuka Pharmaceutical Co Ltd, AstraZeneca Co Ltd, Miyarisan Pharmaceutical Co Ltd

References

[1] WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects. Available at https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

[2] Ikeda T, Yoshizaki T, Eguchi T et al. Efficacy of specimen pasting after cold snare polypectomy for pathological evaluation of horizontal margins. Endosc Int Open 2022; 10: E7120–E718

[3] 倫理指針（本文）（平成29年2月28日一部改正 available at https://www.mhlw.go.jp/content/10600000/000757206.pdf