



## Why do journals publish research protocols?

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### Introduction

A protocol is defined as “the detailed plan of the study.” Every research study should have a protocol, and the protocol should be written explicitly [1]. The increasing emphasis on transparency in research has been accompanied by a growing recognition of the importance of research protocols. Furthermore, it is well known that various biases, including publication bias and selective outcome reporting bias, can be reduced through protocol registration. In recent years, there has been a shift from registering research protocols to publishing them. This article describes the reasons for publishing research protocols and the foreseeable impacts of this trend.

### Registration of Research Protocols

According to the Declaration of Helsinki, “Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject” [2]. The most important reason for pre-registration of study protocols is that human subjects research carries risks to patients. However, a significant number of human studies have not been published. For instance, it was reported that 31% of studies conducted for Food and Drug Administration approval were unpublished, and the results of unpublished studies were mostly negative [3]. Selective outcome reporting is another problem with the non-publication of research. According to the same study, 62% (51/82) of 102 protocols for clinical trials approved for antidepressants showed that the actually reported outcome variables were different from those of the original protocols [4]. Furthermore, the International Committee of Medical Journal Editors mandated the registration of all clinical trial protocols [5].

### Publication bias

The first reason why protocols should be registered is to prevent publication bias. Publication bias means that reviewing only published research results leads to an overestimation of the research results. Publication bias occurs because more positive results lead to more submissions, more publications, and a more rapid turnaround time for publication. For example, 13 studies were conducted on the effect of reboxetine, a drug for major depression, but only four of them

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were published. If the overall results were analyzed instead of only published data, the effect of this drug on depression would be greatly reduced, and the possibility of dropping out due to side effects would be twice as high [6]. Registering all protocols significantly reduces the risk of publication bias.

### Selective outcome reporting bias

The second reason why protocols should be registered is to reduce the risk of selective outcome reporting bias, which refers to the reporting of only positive outcomes related to the effect of a specific intervention. There are two types of bias in selective outcome reporting. The first involves reporting only some of the measured specific intervention outcomes (i.e., selective reporting of specific intervention outcome measurements), and the second involves reporting only part of the analyzed content (i.e., selective reporting in the analysis).

### Advantages of protocol registration

Registering a protocol has several advantages, the most important of which is avoiding publication bias and bias due to selective reporting of intervention results. Registration also avoids unnecessary duplication of research, improves the clarity of conduct and analysis of research, informs ongoing clinical trials, and protects authors' rights in research.

## Protocol Registration versus Protocol Publishing

For some time, protocols were subject to registration, not publication. However, this trend has recently been changing. A search for "protocol [ti]" in PubMed (<https://pubmed.ncbi.nlm.nih.gov/>) shows a sharp increase from 469 results in 2000 to 9,815 in 2021. The purpose of protocol publication may differ slightly according to the researcher's point of view, the point of view of academia, and the point of view of society as a whole (Table 1).

### Issues Related to Protocol Publishing

Several issues are related to protocol publication. The first is the emergence of protocol-only journals. Several international journals are launching journals that only publish protocols, like spin-offs. For example, *Nature* publishes a journal called *Nature Protocols*, and *JMIR Research* publishes a protocol-only journal called *JMIR Research Protocols*.

The second issue is whether protocol registration or publication will predominate. Although this is not easy to predict, from the author's point of view, there is a possibility that there will be a push toward publication, since authors receive credit for publications. Furthermore, since protocol publication is easy to manage and promote in the academic world, publica-

**Table 1.** Purpose of protocol publication

Group	Perspective
Individual researcher	<ol style="list-style-type: none"> <li>1. Protocol publication is favorable for future publication.</li> <li>2. Some journals require publication.</li> <li>3. Some journals offer automatic registration.</li> <li>4. Authors can receive additional credit.</li> <li>5. Methods can be improved through initial feedback.</li> <li>6. Some journals cover the publication cost.</li> <li>7. Some journals discount the publication cost.</li> </ol>
Academia	<ol style="list-style-type: none"> <li>1. Protocol publication provides the institutional review board with data on the current study.</li> <li>2. The publication time is reduced.</li> <li>3. Methodological errors and similar issues can be detected at an early stage and can be corrected.</li> </ol>
Society	<ol style="list-style-type: none"> <li>1. Research transparency is increased.</li> <li>2. Publication bias is prevented.</li> <li>3. Selective outcome reporting bias is prevented.</li> <li>4. Duplication of research is avoided.</li> </ol>

tion may be advantageous.

The third issue is the possibility of publishing protocols in domestic journals in various countries. At the moment, no Korean academic journals publish protocols. However, publication of a protocol guarantees at least one citation, so it can be a breakthrough strategy for journals that want to increase their citations or suffer from a shortage of manuscripts.

## Conclusion

Registration of research protocols has been essential for clinical studies to reduce or minimize the risk of publication bias and selective outcome reporting bias. The advantages of protocol registration include preventing duplicate research, enabling more explicit research conduct and analysis, informing ongoing clinical trials, and protecting authors' rights in a clinical study. There has also been a recent trend for protocol publication, and journals that only publish protocols have appeared. It is time for local clinical journal editors to consider whether they should publish research protocols more actively. Academic society publishers in the medical field should also consider publishing protocol-only journals.

## Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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## References

1. World Health Organization (WHO). Regional Office for the Eastern Mediterranean. A practical guide for health researchers [Internet]. Geneva: WHO; 2004 [cited 2022 Jun 14]. Available from: <https://apps.who.int/iris/handle/10665/119703>
2. World Medical Association (WMA). WMA Declaration of Helsinki: ethical principles for medical research involving human subjects [Internet]. Ferney-Voltaire: WMA; 2018 [cited 2022 Jun 14]. Available from: <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>
3. Shinohara K, Tajika A, Imai H, Takeshima N, Hayasaka Y, Furukawa TA. Protocol registration and selective outcome reporting in recent psychiatry trials: new antidepressants and cognitive behavioural therapies. *Acta Psychiatr Scand* 2015;132:489-98. <https://doi.org/10.1111/acps.12502>
4. Chan AW, Hrobjartsson A, Haahr MT, Gotzsche PC, Altman DG. Empirical evidence for selective reporting of outcomes in randomized trials: comparison of protocols to published articles. *JAMA* 2004;291:2457-65. <https://doi.org/10.1001/jama.291.20.2457>
5. International Committee of Medical Journal Editors (ICMJE). Recommendations [Internet]. ICMJE; 2022 [cited 2022 June 14]. Available from: <https://www.icmje.org/recommendations/>
6. Eyding D, Lelgemann M, Grouven U, et al. Reboxetine for acute treatment of major depression: systematic review and meta-analysis of published and unpublished placebo and selective serotonin reuptake inhibitor controlled trials. *BMJ* 2010;341:c4737. <https://doi.org/10.1136/bmj.c4737>