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Editorial

SPIRIT 2025 and CONSORT 2025 statements: guidance tools to ensure clinical trial transparency

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Two widely endorsed and useful guidelines have recently been updated to improve the capabilities of investigators in planning and reporting randomized clinical trials (RCTs): the SPIRIT 2025[1] and CONSORT 2025[2] statements. This is the first update of SPIRIT which was first issued in 2013. This is the third update of CONSORT, updated in 2001 and 2010 after it was first published in 1996. These two statements have a clear didactic function and include checklists of items to guide trialists on protocol development (SPIRIT) and on post-trial reporting (CONSORT). The ultimately goal of these guidelines is to ensure that trials provide robust data that are appropriately reported in a transparent manner: these are the only ways to avoid research waste and to support evidence-based medicine. Yet, none of these guidelines help to

evaluate the social and scientific value of RCTs —a task to be addressed by other stakeholders such as funders and research ethics committees (RECs).

Since the modifications introduced in the SPIRIT 2025 and CONSORT 2025 checklists have already been published,[1,2] it may be more useful to discuss some aspects, notably individual participant data (IPD) sharing, patient and public involvement (PPI) and two critical research ethics issues which merits future inclusion.

For the first time both checklists include an item concerning deidentified IPD sharing. While SPIRIT 2025 reminds trialists to include in the protocol where and how IPD (including statistical code and data dictionary) will be accessible,[1] CONSORT 2025 requires reporting on where the same information can be accessed.[2] This common approach will require trialists to plan on how to share IPD, or to make public to research ethics committees (RECs) and funders at protocol review and to readers of the article reporting their findings, the decision made. Deidentified IPD sharing is critical for Spanish trials since evidence shows that most prestigious Spanish medical journals do not include a data sharing declaration.[3] Even when declaring on data sharing the vast majority of authors do not host IPD on a public and open repository[3,4] —the only way to ensure free access for third parties.[5]

For the first time also, both checklists include an item on PPI. SPIRIT 2025 asks investigators to include in the protocol details or plans for PPI in the design, conduct and reporting of the trial;[1] CONSORT 2025 requires the inclusion of the same information in the manuscript to be published.[2] PPI has several positive effects on RCTs, from identification and prioritization of research topics to dissemination of results.[2] Although PPI has been seriously considered in the UK

and the USA for some time, this has not been the case elsewhere. Studies show that the percentage of trials reporting PPI can range from 5% in Australia[6] to 18% in large intensive care unit trials.[7] A systematic review on non-commercial non-pharmacological Spanish trials showed that only 3.6% of trials reported PPI.[8]

Research ethics has, unfortunately, been somewhat downplayed in the updated 2025 statements. Yes, SPIRIT has an “ethics” section covering REC approval and other topics but has removed an appendix included in SPIRIT 2013 titled “informed consent materials,” i.e., model informed consent form (ICF) and other documents to be given to participants. Having an appendix on ICF in SPIRIT 2025 seems necessary, especially after the 2024 Declaration of Helsinki (DoH) calls for all medical research investigators ─regardless of their academic degree─ to follow its tenets.[9] Many non-medical investigators (eg, psychologists, physiotherapists, dentists, nutritionists) may not be aware that they should follow DoH principles when conducting an RCT.

While in both versions of the SPIRIT 2013 and 2025 checklist there is an item on plans for REC approval, in CONSORT 2025 there is no mention of this. This is derived from the decision taken by CONSORT 2010[10] authors that stated that including an item on approval by an REC is not necessary because ‘funding bodies strictly enforce’ it and medical journals ‘usually address’ it in their instructions for authors. These statements are not correct when considering RCTs at the global level. First, many trials are not funded.[4,8] Second, having a requirement in the instructions for authors does not mean that all articles comply with it ─as has been repeatedly shown with regards to preregistration of trials.[11,12] CONSORT 2025 should be amended to include an item requesting

that the name of the REC that approved the RCT, REC trial ID, and the date of approval be reported.

The various versions of SPIRIT or CONSORT have never included a checklist item on whether the RCT will comply or has been conducted in accordance with DoH principles. Since the DoH was directed at physicians, previous SPIRIT and CONSORT statements versions did not consider it necessary to include an item on this matter. But these statements are applicable to trials conducted by physicians and nonphysicians and, as previously mentioned, the 2024 DoH calls for all medical research investigators to follow their principles. Failing to include an item in SPIRIT 2025 and CONSORT 2025 —both issued after 2024 DoH—, on fulfilment of DoH tenets is inadequate. Inclusion in SPIRIT would allow the REC and the funder (if any) to know whether the trial will comply with DoH principles. Inclusion in CONSORT will allow peer-reviewers to ask about it if it is not reported in the manuscript describing trial results and will ultimately inform the readers of the article.

SPIRIT 2025 and CONSORT 2025 authors have forgotten the importance of ensuring the highest standards in all RCTs in these two important aspects of research ethics. While RCT methodology reporting assessed with CONSORT 2010 has improved over time,[13] whether the RCT was approved by an REC and complied with DoH principles cannot be evaluated with the current CONSORT 2025 checklist. The high rate of increase in the number of trials in recent years —>50% in nonpharmacological trials,[14] most assessing non-regulated interventions— and growing concerns about research integrity[15] requires SPIRIT and CONSORT authors to consider amending these statements to include in

their checklists items on reports of REC approval and fulfilment of DoH principles.

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