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FAQs



Ethical relationships between
health professionals and **industry**

5. Funding from a pharmaceutical company to conduct or participate in research

I have been offered funding from a pharmaceutical company to conduct or participate in research. Should I accept the funding?

What are the risks and benefits of accepting such funding?

A large proportion of research—particularly clinical research—is industry sponsored. This is in part because there is limited public and philanthropic funding available. In some cases, therefore, interactions between industry and health professionals in the research space may be unavoidable and likely to have benefits for patients and the community.

The reality, however, is that industry funds research in part because this enables it to control the research agenda, including the questions asked, methods used and dissemination and translation of results (e.g., into disease taxonomies, diagnostic and therapeutic algorithms, clinical guidelines). This, in turn, creates and expands the market for their products. Accepting industry funding for research therefore creates the risk that you will simply be contributing to the sponsor's commercial interests. Other risks associated with accepting industry funding for research is that it could impact on your clinical judgment and patient care (e.g., enrolling patients in trials where this is counter to their best interests) and erode public and professional perception of your objectivity, integrity and professional judgement.

Does it matter if the funding is tied to the sponsor's product or research questions?

While industry sponsorship is sometimes untied to particular products or projects, most often, industry will conduct or sponsor research into their own products in line with their own commercial interests. This does not mean that the research is of poor quality (indeed, industry sponsored research is often of very high quality) or that you should not accept funding to conduct or participate in it. You should, however, be aware of the risk that you might be contributing to the sponsor's commercial interests.

Should I accept the offer if it comes with conditions or expectations?

All industry funding comes with some conditions (e.g., regarding timelines, research questions, conduct, outcome measures, sponsors' access to data and authorship). The processes for creating research contracts are established by research and industry peak bodies such as the Australian National Health and Medical Research Council, Medicines Australia and Medicines New Zealand. It is important to ensure that conditions imposed by the sponsor do not impact on the scientific merit and validity, integrity critical evaluation and open dissemination of the research.

Should the sponsor be involved in the design or conduct of the research?

Most industry sponsored research is designed by the sponsor in collaboration with key clinical experts, and industry plays a key role in overseeing research conduct and quality control. From an ethical perspective, the key issue here is that industry involvement does not negatively impact the integrity or scientific merit of the research.

Should the sponsor be involved in or have a say in the interpretation or publication of the research results?

Decisions regarding the analysis, interpretation and publication of research results should be made without influence from the sponsoring company and should rest with investigators (lead investigators in the case of multi-centre studies). In doing so, however, researchers should provide sponsors with the opportunity to review and comment on draft publication, and to request removal of information that might be commercial-in-confidence. Publication of research results, whether positive or negative, is expected, ideally in a refereed journal.

Should company representatives be included as authors on manuscripts?

Any individual who has contributed to a manuscript should be included as an author or acknowledged, even if they are company representatives. The integrity of the scientific literature depends on the ability of readers to understand who has contributed to the research and what affiliations and interests they may have.

Should I accept authorship of manuscripts that I have not contributed to (as a writer)?

No. Only individuals who have a warrant for authorship should be named as authors. So called "guest authorship" is contrary to good publication practice because it misleads readers into thinking that particular—often high status—individuals have participated in writing the article. It also potentially undermines the integrity of the research team and its efforts.

Should the company be acknowledged in manuscripts?

Different journals may ask for different information to be declared, however in general manuscripts (and submissions for publication) should acknowledge:

- all sources of revenue obtained by the authors in relation both to the study and to other studies over the period specified by the journal
- all financial relationships outside the work in question, including grants, consulting fees, honoraria, support for travel, payment for writing or reviewing manuscripts, medicines, equipment and administrative support, board memberships, consultancies, employment, expert testimony, patents, royalties and other benefits unrelated to the reported study.
- any other relationships or activities that may have influenced the work.

Do I need to declare the funding and if so, in what circumstances and to whom?

Yes. Financial compensation or payment to clinician-researchers should be declared to:

- the ethics committee approving the research
- research participants
- journal editors and readers of articles (including articles not directly related to the research)
- audiences of presentations (including presentations not directly related to the research)
- students
- any committees or decision-making bodies of which you are a member—both when becoming a member as part of a “standing” declaration and on a case-by-case basis in relation to specific items under considerations
- employers (e.g., as part of an “external earnings” declaration).

What strategies can I use to accept funding in a manner that is ethically and professionally justifiable?

The following measures should be followed to ensure the research you are conducting with industry support is undertaken ethically and professionally:

- While sponsors can be involved in the planning of the research, all research must have social benefit, scientific merit and validity and be ethically sound.

- Any research project conducted or sponsored by a company should include an investigator with a non-commercial institutional affiliation and be assessed by an ethics committee associated with that institution.
- Financial compensation or payment to clinician-researchers should be approved by a responsible ethics committee.
- Payments from industry should be made to the institution and not to individuals.
- All studies should be registered on an appropriate registry.
- Researchers should not be subject to any contractual agreements that negatively affect the integrity or scientific merit of the research, or the likelihood that its results (positive or negative) will be published and openly disseminated.
- It should be a condition of both agreement to participate by researchers and approval by Human Research Ethics Committees that there is a commitment to make all results (both positive and negative) publicly available.
- Final responsibility for decisions concerning publication of results should be taken by investigators.
- Researchers should not agree to be authors on ‘ghost-written’ manuscripts.
- Researchers should not agree to be “guest authors” on manuscripts to which they have not contributed according to accepted warrants for authorship.
- Industry funding should be disclosed to ethics committees, research participants, collaborators, committee chairs and acknowledged in publications and presentations.



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