

RECOMMENDATIONS FOR CONDUCTING AIS-SUPPORTED RESEARCH IN HIGH PERFORMANCE SPORT

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1. Purpose

To provide recommendations and resources to promote high-quality research.

2. Context

High performance sport research funded, supported and/or undertaken by the Australian Institute of Sport (AIS).

3. High-quality research

The importance of high-quality research is highlighted by the <u>National Health and Medical Research Council</u> (NHMRC) as:

"High-quality research that is rigorous, transparent and reproducible contributes to scientific progress. It is essential for the translation of outcomes into practical and clinical applications and evidence-based policy, delivering the highest possible value for research investment and promoting community trust in scientific findings."

3.1 Importance of high-quality research

Whether questionable research practice is deliberate or unintentional, the outcome is always the same: a waste of research and public funding. Poor quality research has little value for end-users such as the athletes, practitioners, sports organisations and society.¹ Poor methodology may lead to exaggerated and/or inaccurate claims that are ethically questionable. Further, decisions made based on flawed evidence can be harmful. To overcome this potential pitfall, ideas need to be explored with good research methodology to reap the benefits.

Science should be reproducible. According to the manifesto for reproducible science,² "improving the reliability and efficiency of scientific research will increase the credibility of the published scientific literature and accelerate discovery". Munafò et al.² have presented [Figure 1] potential threats to reproducible science that should be considered and addressed to evaluate the robustness of both published research and applications for future research projects.

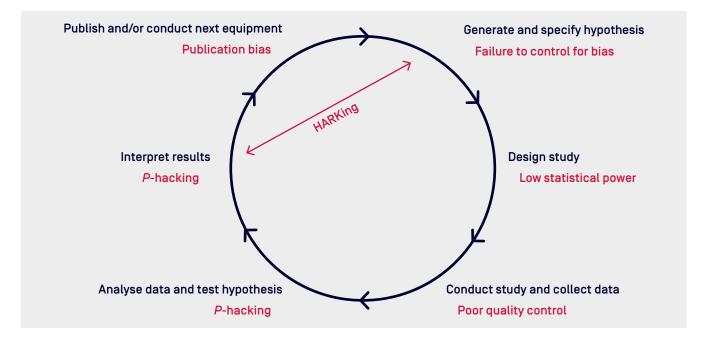


Figure 1. Potential threats to the hypothetico-deductive model of the scientific method (indicated in red): lack of replication, hypothesizing after the results are known (HARKing), poor study design, low statistical power, analytical flexibility, P-hacking, publication bias and lack of data sharing. [From Munafò, M., Nosek, B., Bishop, D. et al. A manifesto for reproducible science. Nat Hum Behav 1, 0021 (2017). Published under <u>CC-by 4.0</u>]

3.2 The role of funders and AIS in promoting high-quality research

Several reports have highlighted the widespread issue of questionable research practices in various research fields.^{3,4} Although the prevalence of this phenomenon in sports science and sport medicine has not been established, it is unlikely that sports research is immune to this problem.⁵ Indeed, a preliminary report by Mesquida and colleagues⁶ has recently shown that publication bias, underpowered designs and lack of open science practices appear to be quite common in high-performance sports research literature. Furthermore, an increasing number of studies in the area of sports science and sport medicine have been retracted for statistically improbable data patterns, data fabrication, duplicate publications and plagiarism, sometimes attracting mainstream media attention.⁷ Although these were mostly cases of a breach of research integrity, rather than poor research practice, this nevertheless underlines that in sports research there is the need for more proactive initiatives to quality control, promote and encourage high-quality research. More incentives embedded into grant funding processes for responsible research in Australian health and medical research have been recently advocated after an analysis of eight schemes from five national funders.⁸ This call suggests nine domains where incentives should be provided (Table 1) and echoes several similar calls from the scientific community for higher research quality, transparency, openness, and reproducibility.^{1,5,9-19} van Calster et al.,¹ recommend a "top-down action from journals, funding agencies, universities and governments is needed to break the cycle. These actions should give methodology a central place in funding acquisition as well as study design, conduct, and reporting."

The implicit contract between science and society is that in return for public assistance, science is expected to transparently produce reliable knowledge and to make it available to society.^{20,21} In alignment with initiatives from Australian funding agencies and organizations (e.g., <u>NHMRC</u>), this document provides recommendations to incentivise researchers toward good research practices⁸ thus promoting high quality research within the high performance sport context, while adhering to all legal and ethical requirements. Table 1. Areas where funders should incentivise applicants (from Diong et al. $^{\rm 8}]$

- 1 Publicly register study protocols before starting data collection
- 2 Register analysis protocols before starting data analysis
- 3 Make study data openly available
- 4 Make analysis code openly available
- 5 Make research materials openly available
- 6 Discourage use of publication metrics
- 7 Conduct quality research (e.g., adhere to reporting guidelines)
- 8 Collaborate with a statistician
- 9 Adhere to other responsible research practices

3.3 Open Science

Open Science is an umbrella term that commonly refers to the process (collection of actions) of making the scientific process transparent and accessible.^{22,23} The AIS encourages open science by establishing research quality indicators (see 5. Recommendations and indicators for high-quality research) based on open science principles (Figure 2). The AIS also endorses the Open Science <u>statement of principle</u> from the Australian Academy of Science that "the advancement of scientific knowledge is best served through the free, open, and accessible distribution of high-quality peer-reviewed research."

For additional information, researchers can also refer to the <u>FAIR</u> principles (Findable, Accessible, Interoperable, Reusable) and the <u>Open Science Training Handbook</u>.



Figure 2. Principles of Open Science (from the Open Social Work initiative; published under <u>CC-by 4.0</u>; original figure <u>here</u>).

4. Reference national policies

Research that is funded, supported or undertaken by the AIS is expected to follow the national policies for responsible research practice and integrity set by the <u>Australian Research Council</u>, as well as the <u>National Statement on Ethical Conduct</u> in <u>Human Research (2007)</u> – <u>Updated 2018</u>, and all legal requirements.

5. Recommendations and indicators for high-quality research

Researchers and people involved in research projects are strongly encouraged to read this document when planning and conducting research. Meeting the current recommendations and demonstrating quality research standards according to established principles can be used as an additional criterion in the assessment of applications for AIS research funding schemes (see specific Grant Guidelines where applicable). In this section, we provide indicators of the responsible research practices (Figure 3) built upon the Hong Kong Principles¹⁸ for researcher assessment and the influential *Series on research waste* published by *The Lancet in 2014*.^{12-16,19} Explanation and elaboration of the quality indicators are also provided. This section also addresses selected critical issues considered more typical or relevant in sports research.

STAGES	CHECKLIST
Study Formulation The study or proposal should specify the type of research (e.g., exploratory or confirmatory) and provide a clear research question addressing a useful and relevant (for stakeholders) matter, built on previous findings.	 Indicators Identification of the type and purpose of research Research priority setting exercise Stakeholder engagement Knowledge synthesis Appropriate pilot and feasibility study
Study Design The design should be coherent and aligned to the research question. The study design should be declared and explained in detail in advance. Practices to reduce publication bias and other reporting biases must be adopted.	Indicators □ Open protocol □ (Pre)registration □ Registered Report
Study Conduct Data collection procedures should allow data aggregation, reuse and transparency. Standard procedures to assure data quality and to make data available (for sharing) should be defined and adopted.	Indicators Quality assurance of data Data sharing Sharing material
Analysis Making the analysis plan and codes available enhances reproducibility and transparency. The analysis plan should also differentiate between data-driven analysis and hypothesis testing.	Indicators Analytical code sharing
Reporting and Publication Accurate, honest and transparent reporting enhances openness and research accessibility. Selective reporting or suppression of study reduces the trustworthiness and integrity of research.	Indicators Transparency Open Access Use of reporting guidelines
Dissemination Wider dissemination of research findings and public engagement with science is an important part of the research process intended to maximise the benefit of research, accelerate the diffusion and implementation of innovations, and transfer knowledge.	Indicators Dissemination and communication plan
Other responsible research practices AIS encourages and values the implementation of any additional practices promoting transparency, openness and rigorous research.	Indicators □ Impact □ Involvement of statisticians and methodologists □ Collaborative research □ Other responsible research practices

Figure 3. Indicators [checklist] for responsible research practice for each stage of the research process [modified and adapted from the Hong Kong Principles, Moher et al.,18 CC-by 4.0].

5.1 Study (and proposal) formulation

5.1.1 Importance of the stage

The study/research proposal should specify the type of research (e.g., exploratory or confirmatory) and provide a clear research question addressing a useful and relevant (for stakeholders) matter, built on previous findings. The study formulation should specify the type of research (e.g., exploratory or confirmatory). Clarity on the type and purpose of the research allows funders, reviewers, and readers to understand whether the methods (and subsequently the interpretation of the results) are appropriate.

Research questions should therefore be identified by involving stakeholders and by examining the previous literature (including examining the risk of bias of previous research syntheses, if used as a reference) in a systematic and methodologically appropriate way. Additionally, the concepts used in the research questions or aims should be described and operationally defined. Aims such as "to examine the usefulness of [intervention and/or technology] in [setting and/or population]" is an example of an inappropriate (too generic) aim using a vague term [usefulness]. Examples of essential elements that should be included in a research question are presented in section 5.1.2 and Table 2.

Research can be conducted in various areas within a continuum ranging from pure basic to applied research [Figure 4]. The AIS is committed to support more user-inspired and applied research.

5.1.2 Indicator: Research priority setting exercise

Choosing the wrong question has been suggested as one of the main reasons for research waste.¹⁷ Referring to or developing a research priority agenda allows the identification of questions that are relevant to stakeholders and the beneficiaries of the hypothesised benefits (normally defined as "research users").

Other than the so-called 'needs-led research agenda', identification of priorities can be based on the burden of a specific problem, cost-benefit considerations, and feasibility.¹²

A <u>report</u> from the James Lind Alliance²⁵ has conveyed that funders are often inclined to operate in a responsive way, i.e. relying on the ideas of researchers instead of setting reference priorities themselves. In 2022, the AIS completed a priority-setting exercise to define its research agenda, namely the National High Performance Sport Research Agenda (<u>NHPSRA</u>). The NHPSRA identified a set of high performance sport research priorities, and corresponding practical research challenges (i.e. subthemes). Within each identified subtheme it is important for researchers to identify the specific research questions needing further research. Examples of frameworks that can be used to develop research questions are reported in Table 2.

An example of a systematic approach to undertake a research priority setting exercise from the World Health Organization can be found <u>here</u>.

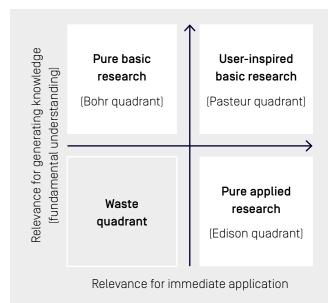


Figure 4. Stokes' Quadrant Model of Scientific Research.24

Table 2. Example of frameworks that can be used to identify the essential information that needs to be reported in a research question forsystematic review but that can also be applied to original research (modified and integrated from Foster, M. & Jewell, S. (Eds). (2017). Assemblingthe pieces of a systematic review: Guide for librarians. Medical Library Association, Lanham: Rowman & Littlefield. p. 38-39, Table 3.3].

Framework (alphabetical order)	Stand for	Disciplines/types of questions (examples, not exclusive)
BeHEMoTh ²⁶	 Be: Behavior of interest H: Health context (service/policy/intervention) E: Exclusions MoTh: Models or theories 	Questions about theories
CHIP ²⁷	C: Context H: How I: Issues P: Population	Psychology, qualitative
PE0 ²⁸	P: Population E: Exposure O: Outcome	Qualitative
PECODR ²⁸	 P: Patient/population/problem E: Exposure C: Comparison O: Outcome D: Duration R: Results 	Medicine
PerSPECTiF ³⁰	 Per: Perspective S: Setting P: Phenomenon of interest/Problem E: Environment C: Comparison (optional) Ti: Time/Timing F: Findings 	Qualitative research
PIC0 ³¹	P: Patient I: Intervention C: Comparison O: Outcome	Clinical medicine
PIC0+ ³²	PICO +: patient values, and preferences	Occupational therapy ('+' was used for consistency with Foster and Jewell, 2017, but not indicated in the original study]
PICOC ³³	PICO C: Context	Social sciences
PICOS ^{34,35}	PICO S: Study type	Medicine
PICOT ³¹	PICO T: Time	Education, health care
PICO for diagnostic tests ³⁶	 P: Patients/Participants/Population I: Index tests C: Comparator/reference tests O: Outcome 	Diagnostic questions
ProPheT ^{37,38}	Pro: Problem Phe: Phenomenon of interest T: Time	Social sciences, qualitative, library science
SPIDER ³⁹	S: Sample P: Phenomenon of interest D: Design E: Evaluation R: Research type	Health, qualitative research

5.1.3 Indicator: Stakeholder engagement

Choosing the wrong research question in medicine is often related to a failure to effectively engage with stakeholders.¹⁷ Research questions addressing relevant problems, interventions and outcomes should be identified together with end-users (e.g., athletes, coaches, support staff and clinicians) in the research ideas generation process.¹⁷ Researchers can also rely on the literature (if available) where research priorities and agendas have been already developed involving the relevant stakeholders.

Stakeholder engagement to generate ideas and identify problems facilitates the development of questions that address relevant matters for the end users of research. Furthermore, research focusing on stakeholders' priorities can facilitate the adoption of research evidence to inform practice, programs, and policies.^{40,41} This can reduce the mismatch between research users' needs and research outcomes, the so-called knowledge-to-practice gap.⁴² Consistent with this indicator, the AIS developed the NHPSRA involving athletes, coaches and practitioners among other key stakeholders.

Design principles to engage stakeholders in research have been suggested by Boaz et al.,⁴³ covering organisational, values and practice domains. Deverka et al.⁴⁴ have proposed a conceptual model for effective engagement of stakeholders in comparative effectiveness research. Whatever the method and level of engagement, the direct or indirect involvement of stakeholders is recommended, and their perspective should be taken into consideration when defining the research question and the aims of the project.

Box 1. Definitions from Deverka et al.⁴⁴

Stakeholder

Individuals, organisations or communities that have a direct interest in the process and outcomes of a project, research or policy endeavour.

Engagement

An iterative process of actively soliciting the knowledge, experience, judgment and values of individuals selected to represent a broad range of direct interest in a particular issue, for the dual purposes of: creating a shared understanding; making relevant, transparent and effective decisions.

5.1.4 Indicator: Knowledge synthesis

Using prior knowledge and the available evidence is essential to identify areas of investigation, inform and guide study designs, and define the analysis. Similarly, if hypotheses are presented, they should be based on and elaborated from previous knowledge, with assumptions presented and properly supported. New studies should be undertaken to answer questions that cannot be appropriately addressed with the available evidence, and replication should not be unnecessary duplication.¹⁷

The examination of what is already known or currently in the process of being researched is fundamental when deciding what further research to conduct.¹² According to Chalmers et al.,¹² the (systematic) assessment of the existing research can also help to avoid redundant duplication and identify what, instead, can be closely or conceptually replicated, eventually addressing methodological weaknesses of the previous investigations.

It is important to be aware that replication is not the rationale for unnecessary duplication. Deciding when replication is necessary or when it instead becomes a redundant study is a matter of perspective, and it can be somewhat subjective. Nevertheless, the decision should be motivated and informed by the existing quantity and quality of the evidence. This can be assessed by systematically and accurately revising the available peer-reviewed literature.

Systematic assessment of the knowledge synthesis

When conducting a systematic assessment of existing evidence on a specific topic, it is possible to rely on available systematic reviews and meta-analyses. However, it is important to take into consideration the methodological quality of the review and, eventually, the appropriateness of the meta-analytic methods used. A PubMed search using the key terms (systematic review) AND (sport OR athlete) shows that the publication of systematic reviews are exponentially increasing since 1975, with 2707 reviews published in 2021 (Figure 5). Quantity is not necessarily paralleled by quality and the critical assessment of the risk of bias of the reviews is necessary [using, for example, tools such as the AMSTAR 2]. Similarly, the evaluation of the quality of reporting can provide insight into whether the essential study information has been provided. Quality of reporting can be examined using guidelines such as PRISMA and its extensions (https:// prisma-statement.org/], as per Indicator 5.5.4. A PRISMA explanation document for sport and exercise has been recently published⁴⁵ and available <u>here</u>. Finally, it is also important to confirm whether the risk of bias assessments normally included in the selected systematic reviews are accurate. This final step is important, due to the fact that valuable information from systematic reviews (with or without meta-analysis) is the evaluation of the risk of bias in previous research (which allows to identify methodological flaws of the available evidence]. Any methodological flaws can inform and guide the design of the new research project and help define the methods that will be used to address previous shortcomings. However, if the methodological issues of previous literature have not been properly examined and identified, this can potentially negatively influence the selection of the methods for the new research and eventually also challenge whether the research question is still relevant.

5.1.5 Indicator: Identification of the type and purpose of the research

Researchers must transparently declare whether the research is exploratory or confirmatory. Both types of research have specific and important roles in science; e.g., exploration can inform and help create testable hypotheses and theories that can be subsequently verified with confirmation studies.⁴⁶

Additional specifications should be provided to indicate for example, whether the research aims to describe, predict, infer causation (counterfactual prediction), validate (e.g., a technology, an outcome measure, etc), and/or whether it is prognostic or diagnostic-type research.

Other kinds of research (e.g., qualitative) and fields may not align with the classifications above, where concepts can have different meanings. For example, explanatory research can rely on mathematical proofs or logical arguments developed with deductive, inductive, or abductive reasoning.⁴⁷ Nevertheless, researchers are encouraged to refer to established guidelines and frameworks of their specific discipline to unambiguously identify the type and purpose of the research.

Confirmatory and exploratory research

According to Wagenmakers et al.,⁴⁶ studies can be placed on a continuum between pure exploratory, where the hypothesis is derived from the data, to purely confirmatory, where the entire analysis is pre-planned (see Table 3).

"Confirmatory analysis refers to the kind of statistical analysis where hypotheses that were properly deducted from a theory and are tested with all statistical parameters defined beforehand. On the other hand, in exploratory analysis, statistical analysis is employed after data collection without any clear theory-driven hypothesis in mind and in the absence of predetermined statistical parameters."⁴⁶

An exploratory study starts without a specific hypothesis and is useful for developing theories (hypothesisgenerating). The reason why a project is based on explorative research should be explained. Furthermore, when a study is exploratory the same data cannot be used for confirmation.⁴⁸ It is important that researchers clearly state not only if the study is exploratory or confirmatory, but also what part of the study is confirmatory and what part is exploratory when these two approaches are used in the same study or project. Since exploration increases the risk of false positive results.⁴⁹ researchers should interpret results according to the limitations of the approach. Stating in advance the type of research prevents poor research practice such as HARKing (Hypothesizing After the Results are Known).⁵⁰

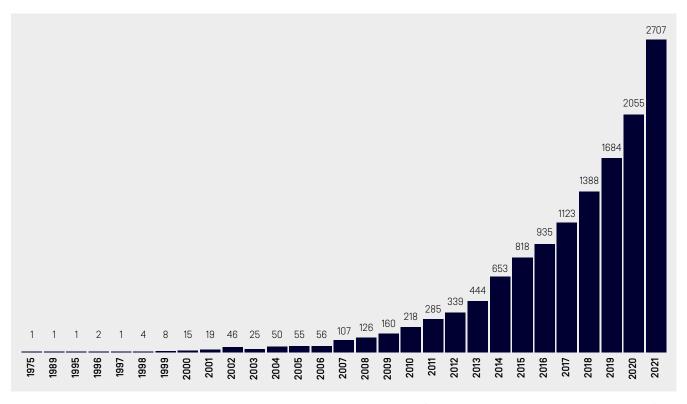


Figure 5. Exponential growth of PubMed articles containing "systematic review" AND (sport OR athlete) in the title or abstract published since 1975.

 Table 3. Characteristics of confirmatory and exploratory research according to the <u>Center for Open Science</u>.

Confirmatory Research

- Hypothesis testing
- Results are held to the highest standards
- Data-independent
- Minimizes false positives
- P-values retain diagnostic value
- Inferences may be drawn to wider population

Exploratory Research

- Hypothesis generating
- Results deserve to be replicated and confirmed
- Data-dependent
- Minimizes false negatives in order to find unexpected discoveries
- P-values lose diagnostic value
- Not useful for making inferences to any wider population

Descriptive, predictive, or causal research

Studies can be designed with three aims: describe, explain [e.g., causal inference], or predict.⁵¹⁻⁵³ Failure to declare in advance the aim of the study may produce erroneous and biased interpretations, and provide misleading information to research users. This problem has been highlighted in sports medicine and statements calling for more transparent and explicit declaration of the research aim, for example, in injury research have been recently published.^{54,55}

Descriptive research summarises the characteristics of a group of individuals,⁵⁶ provides a quantitative summary of features of the world,⁵² and summarises and captures the data structure.⁵³ Exploration of associations (e.g., between variables or between exposure and outcome) without a pre-defined reference framework (e.g., causal assumptions) is an example of descriptive study. Being explorative, interpretations of the associations are tentative, and eventually results can be used to generate hypotheses that will be verified through confirmatory studies.

Explanatory research aims to test causal theories⁵³ using experiments or observational data. In observational studies, the theory provides the causal structure to generate specific hypotheses that will drive the selection of the design and analysis (confirmatory research).⁵¹ Experimental confirmation provides the strongest evidence of causality. However, when using observational designs, the use of causal inference methods based on explicit casual frameworks, theory driven, provides much stronger conceptual support to the hypothesised causal theory than post hoc (ad hoc) interpretation.⁵⁷

Predictive research aims to predict new or future (e.g., in forecasting) observations.⁵³ In prediction, causality is usually not relevant (i.e., not a requirement), and results should not be interpreted as in explanatory or aetiological research (i.e. the variables in the prediction model should not be interpreted as causal factors).⁵⁸ Prediction model development is part of explorative research (no hypothesis is needed), while independent external validation can be considered confirmatory even if the new data can be used to refine and eventually improve the previous model (i.e. they can include an explorative part).

An example of a framework to help researchers understand and/or classify the type of research is presented in Figure 6 (modified from Kent et al.).⁵⁹

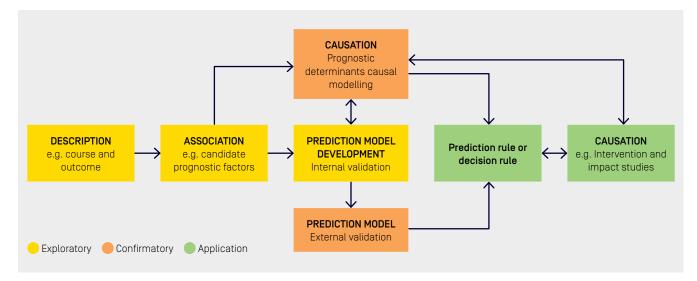


Figure 6. Prognostic research framework [Modified from: Kent, P., Cancelliere, C., Boyle, E. et al. A conceptual framework for prognostic research. BMC Med Res Methodol 20, 172 [2020]. Published under CC-by 4.0]

Replication

The important role of replication in science is unquestionable, and unquestionable is the replication crisis, which is the failure to replicate previous findings.⁶⁰ Funders tend to emphasise novelty over verification.^{2,61,62} Nevertheless, the credibility of scientific claims and the robustness of scientific knowledge is supported by evidence of replicability of the original findings (using new data].^{63,64} Replication is different from reproducibility or computational reproducibility (retesting a claim using the same analyses and data) and different from robustness [using the same data but different analyses].⁶⁴ All these characteristics contribute to produce reliable knowledge and trustworthy science. The references used in this subsection can provide the reader an overview of what is a replication study, and suggestions to understand what and when to replicate.⁶³ A protocol for selecting studies to replicate specific to sports and exercise science is also in elaboration.⁶⁵ Replication studies are well suited to be published as Registered Reports [see indicator 5.2.5].

5.1.6 Indicator (additional): Appropriate pilot and feasibility studies

Pilot and feasibility studies can be presented or conducted to support a research project by assessing the practicability and acceptability of the processes, methods, procedures, resources, and management.⁶⁶⁻⁶⁸

Researchers should be aware that pilot studies are not just underpowered studies. This misconception is common in other fields such as clinical medicine.⁶⁶ Similarly, the use of pilot studies to calculate the sample size needed for the main study is discouraged because the small sample can produce biased and imprecise estimates.⁶⁶ Even when the researchers want to calculate estimates, which is neither required nor recommended, these figures should not be used to make a formal decision about the main study.⁶⁹ El-Kotob and Giangregorio⁷⁰ recommended that researchers in the field of sport and exercise, physical activity and rehabilitation should design, conduct, and report pilot and feasibility studies following the same standards as any high-quality research, and should use published reporting guidelines for pilot and feasibility studies.^{70,71}

What is a feasibility study?

"A feasibility study asks whether something can be done, should we proceed with it, and if so, how."⁶⁸

According to the National Institute for Health and Research <u>glossary</u>, feasibility studies are used to estimate important parameters that are needed to design the main study, such as willingness of participants to be randomised or recruited, follow-up rate, response rate, time needed to collect and analyse data, etc.⁶⁸

What is a pilot study?

"A pilot study is a study in which a future study or part of a future study, is conducted on a smaller scale to ask the question whether something can be done, should we proceed with it, and if so, how."⁶⁸

According to the National Institute for Health and Research <u>glossary</u>, "pilot studies are a smaller version of the main study used to test whether the components of the main study can all work together. It is focused on the processes of the main study, for example, to ensure that recruitment, randomisation, treatment, and follow-up assessments all run smoothly." A pilot study is very similar to the main study. If it represents the first phase of the main study and data contribute to the final analysis, it is called an *internal pilot*. If the data are analysed and used separately [set aside], it is defined as an *external pilot*.⁶⁷

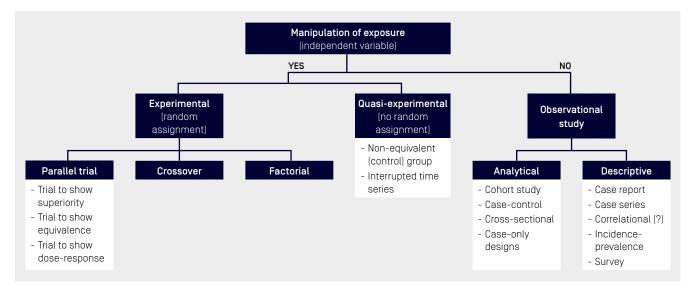


Figure 7. Research design framework for quantitative research.

5.2 Study design

5.2.1 Importance of the stage

The study design has been defined as "a framework, or the set of methods and procedures used to collect and analyse data on variables specified in a particular research problem."⁷² The design of a study should be coherent and align with the research question. Furthermore, as for study type and nature (e.g., explorative, confirmatory, predictive, etc.), the study design should be declared and explained in detail in advance. Similarly, practices to reduce publication bias and other reporting biases should be adopted. This enhances reproducibility and transparency. An example of a research design framework is presented in Figure 7.

5.2.2 Methodological considerations and tools

When designing a study it is advisable to seek input from experts. Specific knowledge in the area of investigation is needed to develop relevant research questions and use appropriate procedures (e.g., for measurements). Similarly, developing a proper research design requires specific expertise and knowledge, e.g., from an expert in trials, prognostic models, causal inference, etc. Conducting research with a weak design and with methodological flaws produces unreliable and invalid results, causing a waste of resources and it is an ethically questionable practice even if it happens involuntary (e.g., due to honest error).

Most studies involving exercise as an intervention are pragmatic trials (or practical clinical trials). Tools for helping and guiding researchers to develop pragmatic trials have been published⁷³ and are available online (<u>PRECIS</u>, PRagmatic–Explanatory Continuum Indicator Summary). Similarly, tools and resources to improve how clinical trials are conducted and managed have been developed by the NHMRC and are available <u>online</u>. Although intervention studies conducted in sports research may not be, technically, clinical trials, the principles are the same. Another important initiative "to provide accessible and accurate guidance in the design and analysis of observational studies" is represented by the STRATOS (<u>STRengthening Analytical Thinking for</u> <u>Observational Studies</u>).

Sampling

In sports research, several studies are observational in nature. Particular attention is needed when sampling participants for these kinds of studies. Failure to do this properly can severely compromise the study's validity. As an example, in case-control studies (commonly used in sports research), controls must be sampled from the same source population of the cases.⁷⁴⁻⁷⁷ Sampling is also linked to the concept of representativeness. Due to the debate about the role of representativeness in different research designs (observational and experimental), it is advisable to be familiar with some of the discussions among epidemiologists and trialists (see for example Rothman et al.⁷⁸). Regardless of the personal preference, clarifying the context (e.g., scientific or statistical inference) is helpful to appreciate the rationale behind the sampling methods used. Accordingly, details on the sampling methods and their justification should be clearly and transparently presented in the study protocol.

Sample size and study power

In sports research, the use of small samples (n < 20)is common.^{6,79-81} Similarly, pre-study power analysis is rarely reported and when reported not all the information on which the calculations are based is provided.⁸² This includes the failure to report the smallest effect size of interest and its justification.⁸² A low sample often implies unreasonably expected large effects or very high associations. The sample size must always be justified for both quantitative and qualitative research.^{83,84} The sample size should also be estimated for feasibility and pilot studies.⁸⁵ However, the effect size from pilot studies should not be used to estimate the sample size of the main study.^{66,69,86} Similarly, the use of rules of thumb for sample size calculation (e.g., for prediction models) is also not recommended.^{87,88} Finally, post hoc power (unfortunately frequently reported in sports research) should not be calculated and reported because these are irrelevant and not useful.⁸⁹⁻⁹¹

Reporting of study protocols

Protocols should be presented according to reporting guidelines, when available [e.g., <u>SPIRIT</u> and <u>PRISMA-P</u> for systematic reviews; see list on the <u>EQUATOR</u> website].

Missing data

The study design should describe how missing data will be handled and what preventive strategies are adopted. Sensitivity analysis to show the effect of missing data handling should also be defined in the planning phase.⁹²⁻⁹⁴

5.2.3 Indicators: Open protocol

The study protocols should be made publicly available as soon as possible. Open protocols provide access to the research methods used in the study that should be reported in a detailed, unambiguous, and transparent way, to facilitate replication.

5.2.4 Indicators: (Pre)registration

The benefits of preregistration are well known and include preventing (or limiting) questionable research practices such as HARKing (hypothesising after the results are known), p-hacking and data dredging, and selective reporting.^{2,50,95-97} Pre-registration is particularly relevant for confirmatory studies. Nevertheless, the preregistration of explorative studies is possible and encouraged.⁴⁸ Registration by itself does not ensure quality (and it can be manipulated as well)⁹⁸ but it promotes transparency and limits the aforementioned poor research practices. This can be achieved by not only pre-registering the basic study information, but also by pre-specifying the study design, primary and secondary outcomes, data collection procedures and analysis plan according to the previous quality indicator (5.2.3).²

Design and analysis plans can be uploaded to public independent registries and repositories such as <u>https://</u>clinicaltrials.gov/, <u>https://www.anzctr.org.au/, https://</u>aspredicted.org/ and <u>https://osf.io/</u>.

5.2.5 Indicators: Registered Reports

"Registered Reports is a publishing format that emphasizes the importance of the research question and the quality of methodology by conducting peer review prior to data collection. High-quality protocols are then provisionally accepted for publication if the authors follow through with the registered methodology." (from the <u>Center</u> for Open Science)

The Registered Report is a relatively new model of publication developed to overcome the outcome bias in science and as an incentive for researchers to conduct replications, and to report negative results.^{99,100} The review process for Registered Reports is divided into two stages.

Stage 1

Researchers submit a manuscript presenting the background literature and study rationale, preliminary work (if any), the reference theory, hypothesis, methods, procedures and analysis plan. The reviewers assess the study proposals before data are collected. If accepted by the journal (i.e., in principle acceptance, IPA is provided), the researchers preregister it, for example in the <u>repository</u> of the Open Science Network.

Stage 2

Once the data is collected, researchers complete and submit the full paper adding the results and discussion sections. The manuscript is then sent back to the same reviewers of Stage 1. The results section includes the outcome of the pre-registered analyses. Any additional unregistered analyses can be added in a separate section under "Exploratory Analyses".

The advantages of the Registered Reports over preregistration are that protocols are reviewed and accepted before data collection avoiding outcome bias and giving the opportunity to identify and correct flaws in the study design before conducting the study. Registered Reports were introduced for the first time in 2013.¹⁰⁰

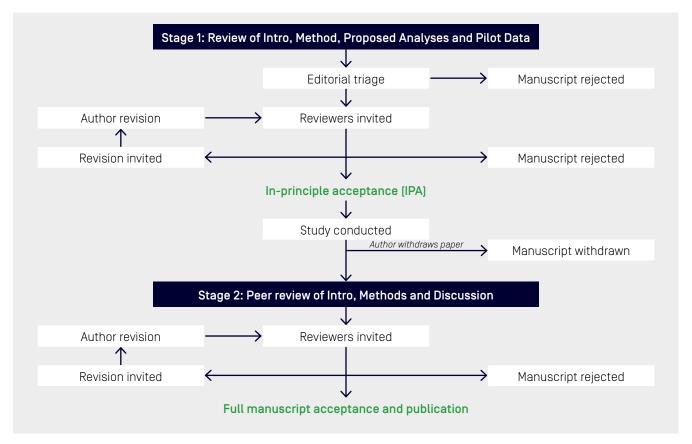


Figure 8. Registered report workflow diagram (from OSF | Center for Open Science; published under CC-by 4.0].

Recently this submission format has been made available in some sports science and sport medicine journals [e.g., Science and Medicine in Football, Journal of Sports Sciences, Human Movement Science, Psychology of Sport and Exercise]. Clarification of misconceptions and realities of Registered Reports can be found in a recent article by Chambers.⁹⁹ Finally, Registered Reports are devised for confirmatory studies. New submission formats such as Exploratory Report have been proposed¹⁰¹ but are not yet widespread and, at the time of this publication, not available in sports science journals.

Researchers are advised to inquire their relevant Ethics Committee about the approval requirement for protocols submitted as a Registered Report.⁹⁹

5.3 Study conduct

5.3.1 Importance of the stage

Data collection procedures should allow data aggregation, reuse and transparency.¹⁸ Researchers should identify and adopt adequate procedures to assure data quality and to make data available (for sharing) where legally and ethically possible. When post-hoc decisions deviating from the registered protocols are made, researchers should rigorously and transparently report the sequence of decisions (and the reasons for those decisions) made during the study.¹⁹

Researchers should also refer to the "<u>Management of Data</u> <u>and Information in Research</u>" published by the NHMRC, the <u>UPSIDE</u> [Uniform Principle for Sharing Integral Data and Materials Expeditiously].

5.3.2 Indicators: Quality assurance of data

Quality assurance is defined in the <u>glossary</u> of the American Society for Quality as "all the planned and systematic activities implemented within the quality system that can be demonstrated to provide confidence that a product or service will fulfil requirements for quality", while quality control is "the operational techniques and activities used to fulfil requirements for quality." Quality assurance is essentially a preventive activity whereas quality control includes activities implemented during and after the data collection.^{102,103} Accordingly, researchers should develop and adopt (standardised) procedures (including training and education) to ensure data integrity during the data collection process in both observational and experimental studies.¹⁰²⁻¹⁰⁵

More details on data quality assurance for clinical registries that can be adapted and generalised to athlete management systems can be found <u>here</u>. Guidelines for clinical research are provided by the International Conference on Harmonisation Good Clinical Practice (ICH-GCP), <u>E6(R2)</u>. Quality assurance procedures for sports and

exercise laboratories are available in the reference AIS textbook, *Physiological Tests for Elite Athletes*.¹⁰⁶

5.3.3 Indicators: Data sharing

Data sharing is a major requirement of open science that favours reproducibility and trust, maximises transparency and public accountability, and reduces research waste.^{18,107,108} According to Bauchner et al.,¹⁰⁹ data sharing is an ethical and scientific imperative that allows data verification and hypothesis generation, in addition to the possibility of increasing the amount of knowledge that can be created from data already collected (thus maximizing the use of resources).¹⁰⁸ Furthermore, the availability of data (and codes) allows the examination of evidence robustness. This indicator applies to both original research and systematic reviews of the literature.¹⁰⁷

5.3.4 Challenges

In some circumstances, it may be difficult to obtain permission from sports organisations and teams to share individual data. In addition, with small samples and identifiable sources (e.g., National teams and single clubs) data re-identification may be possible. Nevertheless, researchers should demonstrate that data sharing [and its benefits) has been considered and eventually discussed with involved parties (athletes, sports organisations, institutions, clubs, etc.]. If data are not made available, researchers should report the reasons (legal, ethical constraints, contractual restrictions, competitive advantage, etc.].¹¹⁰ Similarly, researchers should report what solutions have been considered to address the barriers to data sharing and why each unfeasible solution was excluded. For example, alternatives such as synthetic datasets can be considered and proposed.¹¹¹ Nonetheless, in the case of AIS-funded research. data sharing with the AIS is requested (condition for funding) to allow for checking the reproducibility and robustness of results, if required. Data availability should be clearly reported both in grant applications and in the final publications using a data availability statement (see here for examples of data availability statements).

5.3.5 Resources

To support data sharing, it is recommended that institutions develop and set data management and sharing policies (processes, tools and governance mechanisms).¹¹² Practical solutions for data sharing, including lists of resources, can be found in the <u>article</u> by Gilmore et al.¹¹³ Information and ethical issues on informed consent in relation to data sharing can be found in the guides from the <u>Australian Research Data Commons</u>, and articles such as Ross et al.¹¹⁴ and Meyer et al.¹¹⁵ Researchers can also refer to the <u>open-access policies</u> of the NHMRC.

5.3.6 Indicators: Sharing materials

As for data, sharing research materials increases transparency, reduces research burden and waste, increases efficiency and facilitates replication studies.^{107,116} Materials used for the research can be made openly and/ or publicly available. The materials used to conduct a study are discipline-specific and can include software, athlete or patient-reported outcomes, other psychometric instruments, surveys, assessment tools and devices, prototypes, videos, stimuli, rubrics, scripts, extraction and coding forms, etc.

5.4 Analysis

5.4.1 Importance of the stage

Making the analysis plan and codes available enhances reproducibility and transparency [<u>NHMRC principles</u> <u>of responsible research conduct</u>, P3: "Share and communicate research methodology, data and findings openly, responsibly and accurately"]. The analysis plan should also differentiate between data-driven analysis and hypothesis testing [see 5.1.2].¹⁸

5.4.2 Indicators: Analytical code sharing

Sharing code using repositories such as <u>GitHub</u>, <u>Open</u> <u>Science Framework</u>, <u>Figshare</u>, <u>Harvard Dataverse</u>, <u>Data Dryad</u>, and <u>Zenodo</u> improves the reproducibility of computational methods, transparency and efficiency. Sharing codes (and data) allows examining whether the same analysis (same codes) on the same data produces the same results (reproducibility of evidence) and checking the codes and relative analysis.

Box 2. Definitions from Nosek et al.[2021]^{17} and National Academies of Sciences, Engineering, and Medicine [2019]. ^{118} $\,$

Reproducibility

Obtaining consistent computational results using the same input data, computational steps, methods, code, and conditions of analysis.

Replicability

Replication refers to testing the reliability of a prior finding with different data.

Robustness

Testing the reliability of a prior finding using the same data and a different analysis strategy.

Computation methods

Tools to enable data acquisition, data management, analysis, automation.

5.5 Reporting and publication of AISsupported research

5.5.1 Importance of the stage

Accurate and transparent reporting, regardless of the results, is one of the five Hong Kong principles for assessing researchers.¹⁸ Selective reporting reduces the trustworthiness and integrity of research.^{18,119} Failure to publish all findings of all studies and/or full suppression of complete studies misrepresents the evidence based on which practitioners and institutions make decisions.¹⁸ Selective reporting is also one of the main factors contributing to irreproducible research.^{14,120} Publication bias is a well-known negative effect caused by incomplete reporting that also compromises the findings from meta-analyses.¹²¹⁻¹²⁴ Reporting should meet established guidelines, when available, to facilitate research usability.²

5.5.2 Indicators: Transparent and coherent reporting

Research reports and publications should include all the information that allows reproducing the study, judging its validity and relevance, and using its findings. Six principles of responsible research reporting are presented below, selected from those proposed by Altman and Moher¹¹⁹ and elaborated from the <u>position statement</u> developed at the 2nd World Conference on Research Integrity, Singapore, July 22-24, 2010:

- 1. Researchers should present their results clearly, honestly, and without fabrication, falsification, or inappropriate data manipulation.
- 2. Researchers should describe their methods clearly and unambiguously so that their findings can be confirmed by other researchers.
- 3. Researchers should follow applicable reporting guidelines. Publications should provide sufficient detail to permit experiments to be repeated by other researchers.
- 4. The decision to publish should not be based on whether the results were "positive" or "negative."
- 5. Researchers should adhere to publication requirements that submitted work is original, is not plagarised, and has not been published elsewhere.
- Funding sources and all relevant conflicts of interest (or competing interests) must be disclosed (financial and non-financial).¹²⁵⁻¹²⁷

In addition, to evaluate the quality of reporting of publications of AIS-funded research, the following points are taken into consideration:

- The publications should reflect the methods and aims originally presented in the funded project.
- Whether the study is confirmatory or exploratory

should be clearly reported in the abstract and article conclusions.

- The interpretation of the results should be coherent with the study's nature and its limitations. An example of poor science is when exploratory findings are interpreted and communicated in the form of confirmatory conclusions.⁴⁶
- In recent years, sports research has experienced an increasing interest in prediction models. However, prediction models (assuming they are properly developed and internally validated) should not be proposed for implementation in absence of external validation and, possibly, impact studies.

5.5.3 Indicators: Open access

"Anyone, anywhere in the world should have free, unhindered access to not just my research, but to the research of every great and enquiring mind across the spectrum of human understanding."

-Steven Hawking¹²⁸

Accessibility refers to free access to knowledge and knowledge creation.²³ This can be facilitated by allowing free access to publications, i.e., open access. There are various ways to make peer-reviewed scholarly research freely available (Figure 9). The AIS encourages and values initiatives promoting open science including open access publications. Readers can also refer to the information provided by the <u>Open Access Australasian group</u>.



Figure 9. Typical publishing workflow for an academic journal article (preprint, postprint, and published) with open access sharing rights per SHERPA/RoMEO.[Thomas Shafee, adapted from Ginny Barbour; published under <u>CC-by 4.0</u>]

5.5.4 Indicators: Use of reporting guidelines

Without proper reporting, it is not possible to judge the reliability of results and correctly interpret study findings.¹¹⁹ Lack of proper reporting also limits the ability to assess the risk of bias of the studies included in systematic reviews and limits the efficiency of electronic literature search.¹¹⁹ According to Altman and Simera, "[t]he primary role of reporting guidelines is to help researchers write up their research to maximize the value to others. Adherence to reporting guidelines will increase the completeness and transparency of health research publications, thereby providing readers with sufficient details to enable them to critically appraise the study."¹¹⁹ There are several reporting guidelines for different types of research. These guidelines consist of a minimum set of items (typically presented as a checklist) assisting researchers in writing their study reports and articles. When no specific reporting guidelines are available, it is possible to adapt existing ones which is not ideal (checklists are developed using appropriate methods) but still preferable than not using any checklist.

The EQUATOR (Enhancing the QUAlity and Transparency Of health Research) Network is "an international initiative that seeks to improve the reliability and value of published health research literature by promoting transparent and accurate reporting and wider use of robust reporting guidelines." Researchers can rely on the <u>EQUATOR website</u> to download reporting guidelines and corresponding educational material.

To support the dissemination of the EQUATOR vision, the EQUATOR network also includes regional centres such as the <u>Australasian EQUATOR Centre.</u> The Template for Intervention Description and Replication (<u>TIDieR</u>) is just one remarkable example of the Australasian EQUATOR Centre contribution.

5.6 Dissemination and communication of AIS supported research

5.6.1 Importance of the stage

Wider dissemination of research findings and public engagement with science is an important part of the research process intended to maximise the benefit of research, accelerate the diffusion and implementation of innovations, and transfer knowledge.^{129,130} Nowadays, dissemination can be achieved using communication strategies that are different from the traditional forms common in academic institutions, essentially journal articles, books/monographs, and conference presentations.¹²⁹ Researchers have at their disposal a broader range of options such as various social media platforms, static and dynamic graphical layouts and online discussion platforms.¹²⁹

Ten steps to innovative dissemination

Get the basics right

Define your objectives, map your audience(s), target and frame your messages and bring together into a dissemination plan of what you'll release and when.

Keep the right profile

Use personal websites, social media accounts, researcher identifiers and academic social networks to make you and your research visible.

Encourage participation

In the age of Open Science, don't just broadcast, go for multi-directional dissemination. Invite and engage with others to participate and collaborate.

Open science for impact

Open Access publications and preprints mean more citations. In addition, publishing datasets, software and peer reviews increase your number of citable research outputs.

Remix traditional outputs

Give traditional outputs like research articles and books an impact-boost with accompanying lay-summaries, press-releases, blogs and visual/video abstracts.

Go live

In person dissemination doesn't have to be as stuffy conferences – hit the road and take part in science festivals, science slams, TEDx talks or roadshows.

Think visual

Dissemination findings through art or multimedia interpretations. Let your artistic side loose or use new visualisations techniques to produce intuitive, attractive data displays.

Respect diversity

8

9

10

Research should reach all who might benefit. Respect inclusion in scientific dissemination by creating messages which reflect gender, demography and ability diversity.

Find the right tools

Choose media, format and dissemination strategy based on your communication objectives. Find tool via, e.g. the OpenUP Hub: <u>openuphub.eu/disseminate/services</u>

Evaluate, evaluate, evaluate

Assess your dissemination activities. Are they having the right impact? If not, why not?

Figure 10. Summary of the 10 simple rules presented by <u>Ross-Hellauer et al.¹²⁹</u> (published under CC-by 4.0).

5.6.2 Indicators: Dissemination plan

Dissemination is a process that requires a plan taking into consideration the target audience and setting.¹³⁰ A research proposal should present a clear dissemination plan to reach relevant stakeholders (research endusers). The dissemination strategy should be developed respecting ethical standards, intellectual property issues, and be coherent with the strength of evidence provided by the study findings. Dissemination and communication plans can also include strategies to incorporate new findings and develop evidence-based guidelines and recommendations.

A list of reference frameworks that can be used by researchers to develop the dissemination plan has been presented by Wilson et al.¹³⁰ Ross-Hellauer et al.¹²⁹ and provides ten recommendations (see Figure 10) for innovative dissemination developed within the <u>OpenUP Hub</u> <u>project</u>. Information and recommendations that can help to design a dissemination and communication plan are available in the dedicated <u>online section</u> of the NHMRC.

5.7 Other responsible research practices

5.7.1 Importance of the stage

In this document, various areas and corresponding indicators of responsible research practice promoting high-quality research have been presented. The AIS, however, also encourages and values the implementation of any additional practices promoting transparency, openness and rigorous research.

5.7.2 Indicator: Impact*

In the <u>National Report</u> for Engagement and Impact Assessment (2018-2019) of the Australian Research Council, *impact* is defined as "the contribution that research makes to the economy, society, environment or culture, beyond the contribution to academic research."

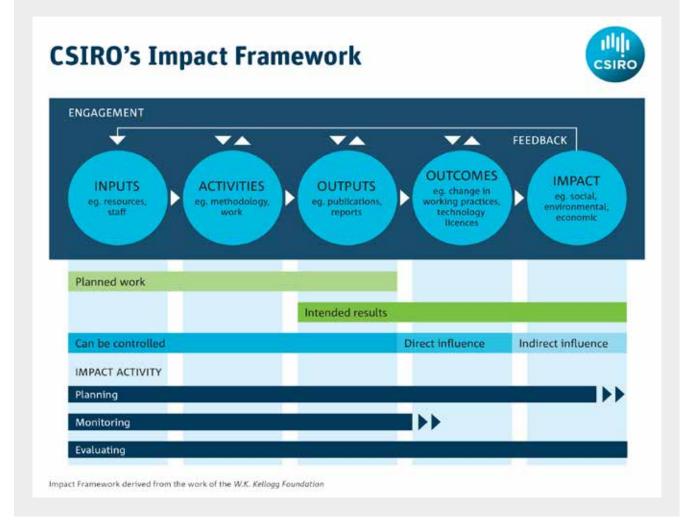


Figure 11. Impact framework [©CSIR0]

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^{*} The dissemination of participant-level datasets and their reuse by other researchers is considered by AIS as a metric of research impact.

Additional value to the proposal is attributed when the impact pathways and potential indicators (measures) are provided to assist the funder (i.e., the AIS) or other researchers to evaluate the impact of the project. A reference impact framework (Figure 11) and related explanations (available online and downloadable) are provided by the Commonwealth Scientific and Industrial Research Organisation (CSIRO; available here). Addressing this indicator does not imply impact research, even if impact research is welcome and can be added to the project. Proposed definitions, typology, methodological framework and theoretical considerations for impact research can be found in the articles by Reed et al.¹³¹ and Greenhalgh et al.¹³² Impact research in this context does not specifically refer to studies examining the (clinical or practical) impact of interventions, predictive/prognostic and diagnostic models^{133,134} although impact studies can be used to evaluate the impact of previous research or as part of the impact pathway.

5.7.3 Indicator: Involvement of statisticians and methodologists

"To consult the statistician after an experiment is finished is often merely to ask [them] to conduct a postmortem examination. [They] can perhaps say what the experiment died of."

-Fisher R.A., 1938

For about a century the lack of involvement of experts such as statisticians in the developing phase of a study is considered a flaw in the research process, often without remedy. This despite evidence that the involvement of statisticians (and epidemiologists) improves the quality of the studies and even shortens the time to publication.135-137 This problem is regularly brought to attention within the scientific literature every few years.¹³⁸⁻¹⁴² A call to increase statistical collaboration in sports science and medicine has been recently published.¹⁴³ The AIS strongly encourages and considers an indicator of high-quality research the involvement of a statistician and/or experts in research methodology (e.g., trialists and epidemiologists), with accreditation, formal education or documented experience. This is necessary not only for original research but also for systematic reviews and meta-analyses. Even when a systematic review does not include a metaanalysis, the evaluation of the risk of bias requires some level of methodological and technical knowledge.

5.7.4 Indicator: Collaborative research

The AIS values collaborative research, i.e., research involving two or more parties (individuals or institutions) or research groups from different disciplines. In collaborative research, different expertise and perspectives are shared and provide benefit to the whole research group. Collaborative research in the form of multicentre studies improves the generalisability of findings and allows reaching larger sample size.¹⁴⁴ Especially for high performance research involving elite athletes, there is an objective difficulty in reaching adequate sample sizes. However, in sports research, the use of a single team and club, albeit common, provides limited information including exaggerated and imprecise effects. This problem can be addressed by conducting multicentre/multiteam studies that are certainly possible even if requiring more coordinating effort.¹⁴⁵ Researchers can also refer to the collaborative research guide of the National Health and Medical Research Council <u>2018 Code</u>.

5.7.5 Indicator: Other responsible research practices

Researchers can implement (and specify) additional responsible research practices that will be considered by the AIS in the evaluation of the merit of research project proposals.

6. Authorship

Authorship should follow established recommendations such as the <u>guidelines</u> by the International Committee of Medical Journal Editors (<u>ICMJE</u>), although some debates exist.^{146,147} National reference authorship guidelines can also be found in the <u>guide</u> provided by the National Health and Medical Research Council <u>2018 Code</u>.

6.1 Group authorship

Authorship in collaborative research can be presented as group authorship. Information about group authorship can be found on the website of the <u>Council of Science Editors</u> and the <u>National Library of Medicine</u>.

6.2 Author contribution

The AIS endorses the inclusion in proposals and publications of the authors' contributions according to the <u>CRediT</u> [Contributor Roles Taxonomy].

7. AIS Ethics Committee

Before conducting research that involves human participants researchers should refer to the AIS Ethics Committee website: <u>https://www.ais.gov.au/research-submissions/ec</u>.

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