Ethical Standards in Sport and Exercise Science Research: 2022 Update

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For publication in the International Journal of Sports Medicine (IJSM), studies must have been conducted in accordance with recognised ethical standards and national/international laws. At submission, authors are required to confirm that these standards and laws have been adhered to by reading this editorial. Authors who do not provide any information regarding ethical approval will have their manuscripts rejected before the peer-review process, without any option to resubmit.

In the original 2009 IJSM editorial [1], we described the ethical considerations embedded into national/international laws and provided specific guidance on the ethical issues which commonly arise in Sports Medicine research. While the four basic principles of biomedical ethics are, arguably, constant and timeless [2], data collection processes, research designs and settings etc. are not and may bring changes to ethical considerations. As a result, the article has been updated five times, prior to 2022, in the areas:

2011 [3] recognition of the ethical principles of other professional associations and treaties for research involving human participants, guidance on the use of Laboratory Animals, and on links between sample size and research ethics.

2014 [4] studies of doping agents, the use of animals where the research questions appeared focussed on the enhancement of athletic performance and sample size in the context of participant burden.

2016 [5] changes to the Declaration of Helsinki, the use of social media in research, feeding back incidental and pertinent findings to participants, issues in studies involving young people, and key differences between full and pilot studies.

2018 [6] clarification of the use of gatekeepers for accessing participant's personal data, informed consent, breaches of confidentiality, use of person identifiable information, open access data and secondary analysis of data and the use of placebos and participant deception.

2020 [7] further detail on informed consent/assent, secondary data analysis, pre-study risk analysis and study design and the application of the *Principle of Justice* [8] (with particular regard to gender imbalance in sampling).

In this 2022 update we have added text on:

- Ethical considerations where the participant's gender and/or sex is a parameter of interest
- The use of remote research methods (including electronic signatures consent and data retention). During the COVID 19 (SARS-CoV-2) pandemic many researchers employed (or changed to, in studies already underway) remote methods of data collection (virtual or on-line). This brought into particular focus the ethical issues involved
- The use of screening tools for eligibility
- Studies testing substances (ingested or non-ingested) and/or, devices or processes hypothesised to improve health and/or enhance performance, that may be harmful and/or risk censure if detected.

We also revise the sequence and structure of the text to enhance readability and usability and reduce areas of overlap.

Research involving human participants

All submitting authors should confirm that research involving human participants has been conducted ethically according to the principles of the World Medical Association Declaration of Helsinki [9]. The Declaration is intended to be read as a whole and every principle is equally important. The principles, most pertinent to the types of research undertaken by sport and exercise scientists, are highlighted below:

Basic principles – Respect for the dignity, rights, safety and well-being of all actual and potential participants, researchers, non-participating members of the public, and the environment takes precedence over scientific, or any other, considerations or interests.

Ethical review – Before any substantive work begins (and before any amendments are made – after ethical approval), the research must be reviewed and approved by the relevant Research Ethics Committee/Institute Review Board (REC/IRB).

N.B. Since the primary purpose of ethical review is to protect the participants, ethical approval cannot be granted retrospectively.

Protocol design – All aspects of the methods must be described clearly and be justifiable and appropriate. In designing their research, researchers must consider:

- ethical issues (with the Declaration of Helsinki as the principle reference),
- potential conflicts of interest and disclosure of any funding and sponsorship arrangements, institutional affiliations, and any other potential sources of conflict,
- the contribution of the work to the knowledge base in the area under study, arrangements for indemnifying participants, including compensation for anyone harmed as a result of participation, arrangements for treatment (or support), both immediate and in the longer term, for anyone injured or harmed as a result of participation.
  - N.B. Researchers are not expected to provide treatment themselves (emergency First Aid/Responder type actions notwithstanding). Rather participants should be advised to seek help from their usual medical provider,
- arrangements for post-study access – by all participants – to interventions identified as beneficial in the study or access to other appropriate care or benefits.

Consent – The potential participant's choice (about participation) should be fully informed, free and private. Informed consent/assent should normally be recorded in writing with justification given for any exceptions. Where consent/assent is given verbally, how and when that consent was given should still be formally documented and witnessed.

Research that involves very young people, or those who are deemed not to have the mental capacity to give informed consent (e. g. vulnerable adults), should (in the UK *must*) involve consultation with an appropriate person and the assent of the participant (wherever the latter is possible).

Research involving participants who are known to lack the mental capacity to give an informed consent may be undertaken only in accordance with local statute e.g. [10, 11]. In addition to all other considerations, the baseline principle that - having the characteristics, that impair informed consent, is a crucial aspect of eligibility (and hence, the research aims could not be achieved, with recruitment from any other population) – is expected to have been met.

Information for consent/assent must be; presented in accessible language/format. The information given must encompass (as a minimum) – the researcher's names and institutional affiliations, the aims of the research (i. e. why the work is being undertake), methods (i. e. what participants will be asked to do), sources of funding, conflicts of interest, anticipated benefits and potential risks, potential discomfort, the right to decline the invitation to participate – without consequence, the right to withdraw consent – without consequence – after consent but before data collection is completed, the right to withdraw data after collection (if applicable), arrangements for data storage, sharing, retention/destruction etc. and contact details for questions and/or complaints

Conduct – Research must be conducted

- in accordance with appropriate risk management (as identified in the pre-study risk assessment)
- by appropriately qualified researchers and support staff
- with skill and care
- in an appropriate setting
- in a way that protects the privacy of participants and the confidentiality of their personal information
- in accordance with applicable statute and frameworks/regulations of the country (or countries) in which the research is to be performed as well as international norms and standards.

NB Country, or region, specific statute and frameworks/regulations often cover: aspects of research ethics, the collection, use and/or storage of human tissue, the protection of individuals that lack the capacity to consent, data access, processing and protection, and the use of drugs in research etc.

Governance – Serious adverse events/reactions, occurring during the research, must be reported to the approving REC/IRB and the Sponsor in a timely period.

Use of Social Media – All research which involves the use of social media to recruit participants, conduct research or as a data source must be reviewed and approved by an appropriate REC/IRB and researchers must adhere to the core principles of informed consent (detailed earlier).

Researchers should address the following issues: the practicalities of providing information, recording consent and collecting/using data; anonymity, privacy and confidentiality in a setting whereby information is publicly available from identifiable sources; the potential for harm and intrusion; data ownership and security; researcher identity.

Pertinent and Incidental Findings – Pertinent findings are related to the variable or primary outcome(s) being studied and incidental findings are not related to the variable or primary outcome(s) being studied. Pertinent and incidental findings may be interesting, or important, to participants. Researchers must decide whether to routinely share such findings with participants and provide clear information on their intentions as part of informed consent. In deciding researchers must consider and respect participant choice and understand and manage expectations. Where findings

will be shared this must be via an adequately resourced participant friendly method.

Participant involvement – In accordance with recommendations made by the Nuffield Council on Bioethics to the Health Research Authority [12], researchers should endeavour to involve young people and parents/guardians, as appropriate, in the design of research. Participant involvement in other aspects of the research such as the dissemination of findings is also good practice.

Research where the participant's gender and/or sex is a parameter of interest – where the participant's gender and/or sex is a parameter of interest (either through eligibility, methodology and/or analysis and outcomes) researchers should consider not only the ethics of inclusivity (for example inter, trans or cis sex individual's eligibility) but also the ability of the reader to contextualise results.

In such study's authors should report how any eligibility criterion and/or analysis, based on gender and/or sex, were defined and validated and discuss not only the scientific, but also ethical, justification for those aspects of the study design.

The use of remote research methods (including electronic signature formats for consent and data retention) –

Online platforms, researchers should consider the nature of platform settings (e. g. possible recording of IP addresses and compliance with applicable Data Protection Legislation).

Researchers should consider their obligation/ability to provide support if required and their obligation/ability to respond to discoveries or disclosures that raise concern (e. g. safeguarding concerns).

Where video conferencing platforms are used researchers should consider participant privacy (e. g. by recording only the audio, if analysis of the video data is not required to meet the stated aims). Researchers must also ensure minimisation/safeguarding of personal data (e. g. interview recordings may be deleted once the transcripts has been confirmed as being valid/accurate and the recording has no further value in the research).

Where informed consent is given verbally and is audio recorded, these recordings should be held separate from study data. Such recordings must be stored in accordance with retention policies. While records of consent may be retained for long periods, researchers must ensure minimisation/safeguarding of personal data.

Where informed consent is recorded using an electronic signature, researchers must consider the different forms of e-signature available and (subject to local legislation) the legal status of each. e-signatures are often classified as 'simple,' 'advanced' or 'qualified'. Researchers must select a classification appropriate to the study. The principles of confidence in written consents, however, apply equally to e-consents, i. e. it remains vital that, the person who signed is who they say they are, the consent form hasn't been altered and when the signature was applied is recorded.

If online questionnaires include the collection of person identifiable data (e. g. where contact details are requested to give incentives or arrange further participation) participants should submit their data responses separately from their personal data.

Principles of professional associations and sources other than the World Medical Association Declaration of Helsinki - Authors may conduct their research in accordance with principles detailed by professional associations and sources other than the World Medical Association Declaration of Helsinki (such as the International Sociological Association's (ISA) Code of Ethics [13]). It is recognised that differences in ethical principles may exist between professional associations and sources, e. g.,

- The ISA's code of Ethics states that "The consent of research subjects and informants should be obtained in advance. Covert research should be avoided in principle, unless it is the only method by which information can be gathered, and/or when access to the usual sources of information is obstructed by those in power." [13].
- The UK Medical Research Council has outlined some basic principles of good research practice which may help to ensure that research is conducted ethically. These include planning, conduct, recording data, reporting and applying results [14].
- Relevant issues, not specifically raised in the Declaration of Helsinki include, for example: the use, calibration and maintenance of equipment, adherence to Control of Substances Hazardous to Health Regulations (and local/National equivalents), documentation of standard operating procedures, retention of data, publication policy, authorship, correction of errors and retraction of published findings and intellectual property rights.

Authors are required to detail and justify, where aspects of their research abide by ethical principles set down by professional associations or sources that differ, in substance, from any of the principles in the Declaration of Helsinki, or this editorial.

Deception – The use of deception in research (e. g. in a pacing strategy study in which time trial distance is deceived) must be minimal and justified:

- Minimal, in that while, in the majority of cases it may be required to conceal the aim/purpose of the study, there is no need to conceal what the participants will be asked to do, and
- Justified, in that no reasonable alternative methods could be used to obtain the data required to achieve the aims. In addition there should not normally be any anticipated pain or emotional distress for participants.

Where there is deception, participants must be accurately informed of the nature, extent and purpose of the deception, as soon as it is reasonable to do so, and given the option to withdraw their data if they wish [21].

The use of screening tools for eligibility – Where readiness to exercise questionnaires, and/or other screening questionnaires are used, researchers should reference those in the article draft submitted for review.

In study design researchers should consider if the screening process was applied to aid scientific rigour or analysis (e. g. to ensure compliance with inclusion/exclusion criteria or for co-variant stratification for analysis) – or – for risk management/reduction.

- If required to manage/reduce risk, the tool must collect person identifiable data and be dated (otherwise the risk factor could not be monitored, nor associated with any individual). The data should be treated as extremely sensitive personal data and processed and accessed in accordance with applicable statute and the relevant retention policy (e. g. Data

Protection Legislation and Institution, Funders, Publishers requirements etc)
- If not required to manage risk, the tool may be dated, but would not normally collect person identifiable data.

Research involving animals

Authors who cite this editorial confirm that research involving animals has been conducted ethically according to the principles of the Guide for the Care and Use of Laboratory Animals of the Institute for Laboratory Animal Research [16]. Again, the guide is intended to be read as a whole, but the basic obligations on the researcher are summarised below. The researcher must:
- Ensure the appropriateness of experimental methods
- Legally acquire animals
- Ensure that animals are properly housed and fed to ensure safe, hygienic and comfortable living conditions
- Maintain a record of animal care
- Ensure that animal maintenance and research are carried out by qualified personnel, following all applicable legal statutes and regulations
- Administer appropriate pain management to minimize suffering, discomfort and pain

The eighth edition of the Guide for the Care and Use of Laboratory Animals [17], published in 2010, includes expanded coverage of the ethics of laboratory animal use, components of effective Animal Care and Use Programmes, new guidelines for the housing, environment, and enrichment of terrestrial and aquatic animals and for veterinary and clinical care [18]. Specifically, an Animal Care and Use Programme, a performance standards approach for animal care and care practices, the care and use of fish and other aquatic species, housing space and enclosures for animals' social needs, environmental enrichment for the enhancement of animal well-being (provision of sensory and motor stimulation and promotion of psychological health) and discussion of animal biosecurity practices

Exercise protocols in animal research – A useful document for any researcher interested in studying animals in an exercise context is the Resource Book of the American Physiological Society [19]. The study of animals can help elucidate the mechanisms of both human and animal exercise – related health benefits. Nevertheless, any animal study that has been specifically designed to answer a research question based solely on the enhancement of human athletic performance, should include a clear justification of both the study's value and the use of animal, rather than human participants. This justification is important, not just from an ethical perspective, but is in keeping with the aim of maximising external validity in any study.

Secondary data analysis projects

Data are routinely collected from individuals for various purposes, e. g. an athlete's physiological function, or health status, may be monitored (and corresponding data recorded) for training purposes. Such data collection may be a contractual obligation. Researchers must consider that data collected for one purpose (e. g. performance monitoring), cannot normally be accessed or processed for another purpose (e. g. research) unless explicit and informed, consent for the secondary data access and processing is obtained (and the research ethically approved), or local derogations permitting such access and processing, without consent, are adhered to. This issue is particularly pertinent (and hence great care must be taken) where the data concerned was collected as part of a contractual obligation. Researchers who are accessing, processing and/or storing data obtained from large accessible repositories should do so according to terms of the repository holder.

Studies testing substances (ingested or non-ingested) and/or, devices or processes hypothesised to improve health and/or enhance performance, that may be harmful and/or risk censure if detected.

Such studies may carry additional risk of harm to participants. Consequently there is a greater imperative to inform participants of the precise nature and likelihood of risks and potential side-effects in a clear and transparent way. The informed consent/assent process must ensure that participants are informed of:
- How to recognise and appropriately respond to any side-effects, or adverse events/reactions, that they may experience, and
- When and how to report any side-effects or adverse events/reactions (expected and unexpected) to the researcher

Researchers must fully report any side-effects, Serious Adverse Event/Reactions, Suspected Unexpected Serious Adverse Reactions etc. and their link to the Protocol and participation, with any study findings.

The inclusion of a placebo group (whether the study involves athletes or not) may challenge the principle of equity and should only occur where there is genuine doubt regarding the efficacy/effectiveness of the intervention under study, any risk of harm is proportionate to the likely benefits and hence no proven treatment or intervention is withheld. In research where participants are patients or clients, extreme care must be taken to avoid the abuse of placebo.

Allocation to the intervention, or placebo groups should be random, with adequate concealment and blinding wherever possible. After a finite length of time those participants in the placebo group *could* be offered the intervention but only where the intervention is in established use and proven to be safe. Studies would normally be terminated early if it became clear (interim analysis being undertaken by an independent Data Monitoring and Ethics Committee) that the placebo group was fairing more poorly [20].

Athletes as participants in studies on doping agents – In principle, recreational and elite athletes should not be recruited to participate in research that exposes them to violations of the World Anti-Doping Code [22]. There can, however, be merit in researching doping in sport. Investigators who wish to recruit athletes in research involving performance enhancing substances and methods should consider the following:
- Consultation with appropriate and relevant authorities (specific to each individual athlete) such as IRB/RECs, World Anti-Doping Agency (WADA), international sport federations and national anti-doping organisations – to help protect recreational athletes, elite athletes and sport.
- An unfair advantage should not be afforded to a recreational or elite athlete participating in the research. "Adequate

precautions should be taken so that the results of research are not misused and applied for doping" [22].
- Append the WADA letter entitled "Scientific research using elite athletes: WADA point of view" [23] to the participant information sheet to help fully inform participants who are recreational or elite athletes.

Ethics and sample size

Authors should consider statistical power and precision in manuscripts submitted for review. Ideally an a priori estimation of the minimal sample size, for adequate power and/or precision of a confidence interval, should be reported. Post hoc statistical power estimations (based on the observed effect size in the study) should be avoided. Authors and reviewers of IJSM manuscripts should be aware of the following important points:

- The minimal sample size for adequate statistical power should be considered in the context of participant burden and the potential importance of the study findings to the knowledge base and practice [24]. Substantial burden is inherently unethical where study findings have no, or dubious, clinical/practical importance. A "small" study may be ethical, however, especially if participant burden is low and clinical/practical importance of the study findings are high, even where "statistical significance" has not been realised.
- Researchers must consider and discuss if an unusually large sample effect size may have arisen through the sampling error associated with a small sample size, sometimes referred to as "The Winners Curse" [26].
- It is imperative that a minimal clinically/practically important magnitude of change, or difference, (MCID), for the primary outcome measure(s) is stated by authors [25]. Authors should also report the associated confidence interval(s), *at least* for the primary outcomes. Authors who rely solely on statistical significance (i. e. the size of a p-value) to judge clinical/practical importance will have their manuscripts rejected. It is important to recognise the difference between the MCID and
  - the minimal detectable effect – the former is the effect size or association that is important – for the population the sample is drawn from - in clinical or practical terms (e. g. improvements to health or performance), and,
  - the latter is the lowest effect size or association that can be detected. with a given precision and sample size.
- There are useful guidelines on what constitutes a pilot or feasibility study, e. g. [27]. Such studies do not necessarily have to be powered to detect a certain effect size. Alternatively, they may be powered to detect, with adequate precision, a standard deviation to ultimately help estimate the required sample size for a substantive trial.

Author obligations

By reading and citing this editorial, the author(s) confirm the following points are upheld [15]:

- The points, principles and practice guidance, contained in this editorial were considered and have been adhered to.
- That consent/assent, to participate was valid, in that potential participants were provided with adequate information, consent/assent was given voluntarily and that those providing consent/assent were competent to do so.
- Where research involved participants who were vulnerable or unable to provide consent, the participants were appropriately identified, approached and recruited, there was justification for carrying out the research with these individuals and additional measures were put in place to ensure the research was ethical and complied with applicable statute.
- Issues of privacy and confidentiality were considered carefully, as matters of ethics and not only to meet minimum legal requirements. Where, "privacy is the protection of control over information about oneself; control over access to oneself, both physically and mentally; and control over one's ability to make important decisions about family and lifestyle in order to be self-expressive and to develop varied relationships" [15]. And confidentiality is when the "participant discloses to the researcher information which the participant regards as confidential or secret [default assumption]; and the researcher undertakes (implicitly or explicitly) not to reveal this information to anyone who does not already possess it." [15].
- Researchers considered their own and the Sponsor's, legal and ethical obligations if privacy and confidentiality are breached.
- If the confidential information that was provided as part of a research study has (or will be) accessed and processed for any other purposes, that confidentiality has been preserved by anonymising the information and that consent for that was obtained, or – where derogations allowing access and processing without consent (for example) are applicable - the terms of those were/will be complied with.
- Risks relating to harm, inconvenience, time and money, as well as any benefits to the participant, to other individuals, to the researchers and organisations were considered in a balanced fashion, communicated to the participants as part of the consent/assent process and appropriately managed.
- Likely variation in participant's reaction to and experience of, interventions, outcome measures etc., arising from not only their physical and mental abilities, but all other known determinants (such as gender, age, physical maturity etc.) were considered in all aspects of the design and methods.
- Participants were not exploited and particular groups were not unfairly excluded from participation.
- There were appropriate governance arrangements and structures in place if participants were asked to donate biological material for use in future research, such as a "biobank". These arrangements should involve appropriate consideration of broad consent, privacy and confidentiality, feedback to the participant of incidental findings, storage of material, commercial involvement, donor involvement, intellectual property rights and local statute.
- Participants were informed of and consented/assented to, all aspects of data access and processing, i. e. the storage of data, including how and where the data are stored, the security of storage, how long data are stored for, what uses the data will have, who will have access to the data (other researchers, institution staff, general public) and any data sharing that may occur etc.

Conflict of Interest

The authors declare that they have no conflict of interest.

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