**Introduction to The AIS Ethics Committee**

The AIS Ethics Committee (EC) is a formally established Human Research Ethics Committee (HREC) that abides by the Australian National Health and Medical Research Council’s (NHMRC) [*National Statement on Ethical Conduct in Human Research 2023*.](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018) This important document is referred to as ‘The National Statement’, or abbreviated to ‘NS’ in this submission form.

The EC was formed in 1987, to take a particular focus on elite athletes as participants in research studies. The primary concern of the EC is to safeguard the rights of athletes as participants (both directly and indirectly) in research studies according to the National Statement. The EC is established to provide national coverage of research studies involving elite athletes and can therefore receive submissions from the National Institutes Network (NIN), National Sporting Organisations (NSOs), other organisations within the Australian Sport Sector and their partners.

**Instructions to Applicants**

Researchers submitting an EC submission form have the following obligations:

* Must obtain a broad understanding of the [[*National Statement on Ethical Conduct in Human Research 2023*](file:///C%3A/Users/KendrickJ/Downloads/National-Statement-Ethical-Conduct-Human-Research-2023%20%2813%29.pdf).](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018)
* Must answer all applicable questions. If a question is not applicable, then please state “not applicable” in the relevant box - do not leave any question blank.
* For marking **Yes/No or N/A** boxes, please place a bold **X** in the required box.
* Keep explanatory answers succinct and stick to the recommended length for answers wherever possible. You should not manually alter any box sizes.
* Take responsibility for submitting the form in a timely manner in accordance with the due dates stated in the [AIS research submission process](https://ais.gov.au/research-submissions).
* Complete the submission checklist and list of attachments.
* Save the form as a **Microsoft Word Document** and refer to the [AIS research submission process](https://ais.gov.au/research-submissions) for information on where to email the form.

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| **Submission Checklist** | **Yes** | **No** | **N/A** |
| Full details of the Principal Researcher have been provided. |  |  |  |
| Application has been signed by the researcher(s)  |  |  |  |
| **Attachments are clearly identified**, numbered and included with the application (as per ‘List of Attachments’). |  |  |  |
| Follow-up counselling has been identified if necessary, and the counselling service specified. |  |  |  |
| The ‘List of Attachments’ has been completed. |  |  |  |
| Endorsement by an **independent medical officer.** |  |  |  |
| Endorsement by an **appropriate statistician.** |  |  |  |
| **Responsible Research Practices** have been addressed. |  |  |  |

For any queries, please contact the AIS Ethics Committee Secretary: ethics@ausport.gov.au

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| **List of Attachments** | **Yes** | **No** | **N/A** |
| Signed letter of **permission to access data** (Question 12.3.11 – 12.3.12) |  |  |  |
| **Supplement or medication testing** documentation |  |  |  |
| **Radiation Approval Application** Form |  |  |  |
| **Participants Information Sheet** |  |  |  |
| **Participant Informed Consent** form template |  |  |  |
| Informed Consent (Organisation) form template |  |  |  |
| Proof of approval for **project funding** |  |  |  |
| All questionnaires, surveys, interview questions and test items |  |  |  |
| Any material that has been translated into a language other than English |  |  |  |
| Verbal scripts, emails or written documents to be used for participant recruitment (including flyers/advertisements) |  |  |  |
| Any other relevant supporting documentation |  |  |  |

*\*Please check the requirements for supporting information to each section, specified throughout this form.*

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| --- | --- |
| **1.0 Submission** |  |
| **Date of Submission** |  |
| **Research Submission ID** | *Field to be completed by Ethics Committee Secretary* |
| **Ethics Approval Number** |  |
| *Only required for minor variations and resubmissions, please include original approval number followed by ‘\_R1’ for first revision or ‘\_R2’ for second revision.* |
| **Project Title** |  |

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| **About the Researchers****Organisation****Contact Details** |
| **1.1 Principal Researcher** |
| Name:  |
| Qualifications:  |
| Phone:  | Email:  |
| Organisation:  | Organisation Postal Address:  |

|  |  |  |  |
| --- | --- | --- | --- |
| **1.2** | **Co-Researchers** | **Organisation(s)** | **Qualifications** |
| 1. |  |  |  |
| 2. |  |  |  |
| 3. |  |  |  |
| 4. |  |  |  |
| 5. |  |  |  |

*\*For sections 1.2 (above) and 1.3.2 (below), please add lines if necessary, or delete lines that are not used.*

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| **1.3 Research Assistants** | **Yes** | **No** |
| 1.3.1 Do you plan to engage research assistants at any stage of your project? |  |  |
| 1.3.1.1 If **YES**, please explain why research assistants are required and provide details of their proposed involvement.*Recommended length: 3 – 4 sentences* |
| **1.3.2 Research Assistant** |
|  | **Research Assistant** | **Organisation(s)** | **Qualifications** |
| 1. |  |  |  |
| 2. |  |  |  |
| 3. |  |  |  |
| 4. |  |  |  |

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| **1.4 Conflict of Interest (NS Chapter 5.3.11 - 5.3.12)** | **Yes** | **No** |
| 1.4.1 Are there any actual or perceived conflicts of interest for the research team?*Note, this includes both financial and non-financial conflicts, for example: direct research interests, direct professional interests, expert testimony, involvement in litigation, holding a leadership position in an organization, providing technical or scientific advice to an organization, and personal or professional relationships.* |  |  |
| 1.4.1.1 If **YES**, please list each COI and state your management strategy: |
| Actual or Perceived COI | Management Strategy |
| 1. |  |  |
| 2. |  |  |
| 3. |  |  |
| 4. |  |  |
| 1.4.2 Does any party involved in participant recruitment have any current or past relationship with any prospective participants or the organisation(s) from which participants are sought? |  |  |
| 1.4.2.1 If **YES**, Please provide details: |
| 1.4.3 What strategies will be implemented to minimise possible perceptions of obligation or pressure for participants to take part in this study?*Address each conflict of interest separately, along with 1 – 2 sentences describing the minimisation strategy to be implemented.* |

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| **1.5 Conflict of Interest – funding bodies** | **Yes** | **No** |
| 1.5.1 Is there any potential or intended monetary gain to be made by any of the research team or their affiliates? |  |  |
| 1.5.1.1 Please elaborate:*Recommended length: 2 – 3 sentences per consideration.* |
| 1.5.2 Do any funding bodies for the project have conditions tied to publication? *e.g. Approval to publish results or approval of wording prior to submission.* |  |  |
| 1.5.2.1 If **YES**, please explain:*Recommended length: 2 – 3 short sentences.* |
| **2.0 About the Project****2.1 Brief Description of the Project** |
| *This section is to provide members of the AIS Ethics Committee with clear understanding of the need for the research, relevant literature and the approach adopted. Please use language that can be understood by those outside of the discipline or profession.**This box is limited in size. Please limit your response to no more than 200 words* |

*\*For section 2.2, please add lines if necessary, or delete lines that are not used.*

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| **2.2 Research objective(s)** |
| This section is to provide members of the AIS Ethics Committee with a clear understanding of the project aims. Please use language that can be understood by those outside of the discipline or profession. Please list your research objectives *Objectives should be 1 – 2 sentences in length.**Note, be mindful of vagueness. The research objective(s) should be described and operationally defined. Objectives 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 vague terms. An example of an appropriate objective would be “to examine the effect of [intervention and/or technology] on [variable X] in [setting and/or population]”.*  |
| 1. |   |
| 2. |   |
| 3. |   |
| 4. |   |
| 5. |  |

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| **3. Project Impact** |  **Yes** | **No** |
| 3.1 What will be gained by undertaking this project?*Recommended length: 2 – 4 sentences.* |
| 3.2 Explain how the benefits outweigh the risks (NS Chapter 1.6 – 1.9).*Recommended length: 3 – 4 sentences.* |
| 3.3 Do you intend to publish, or make public, the results of this project? |  |  |
| 3.4 Please explain to whom, and how, the results of the project will be disseminated *Recommended length 3 – 4 sentences.* |
| 3.5 How will the benefits of the project be implemented?*e.g. What changes will occur as a result of the research and what impact will this have on the daily training environment?**Recommended length: 2 – 3 sentences per benefit.* |
| 3.6 Could the outcomes of this project inform policy, programming or training protocols?*Note, this generally applies to confirmatory research and does not apply to exploratory research.* |  |  |
| 3.6.1 If **YES**, please explain how: *Recommended length: 1 – 2 short paragraphs.* |

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| **4. Research Methods** |
| **4.1 Methodology** |
| 4.1.1 Study Design*Present key elements of the study design. Please include randomisation technique and control type if applicable.* | *Recommended length: 1 – 2 sentences* |
| 4.1.2 Detailed Methodology |
|  4.1.2.1 Test Protocols*Please provide a brief step-by-step protocol for the main test(s) to be performed* |  |
|  4.1.2.2 Surveys or Questionnaires (if applicable)*Please list title(s) of surveys and questionnaires and state their purpose. Please include the survey response range, number of increments and any verbal anchors.**Attach all surveys and questionnaires to this submission.* |  |
| **If Surveys / Questionnaires are listed in 4.1.2.2:** | **Yes** | **No** |
| 4.1.3 Are **ALL** the Questionnaires listed in 4.1.2.2 validated and reliable? |  |   |
| 4.1.3.1 Please provide further information to support your answer:*Recommended length: 1 – 2 sentences per survey/questionnaire type. Please provide justification for using this questionnaire or survey including whether they have been proven as valid and reliable.* |

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| **4.2 Procedural** | **Yes** | **No** |
| 4.2.1 Are the procedures, or their combination, new or innovative (not established) (NS Chapter 3.1)? |  |  |
| 4.2.1.1 If **YES**, please explain which components are new or innovative: |
| 4.2.2 Will this study involve ionising radiation, non-ionising radiation or high intensity sound *(Including DXA)*? |  |  |
| 4.2.2.1 If **YES**, have you sought advice from a relevant Radiation Safety Advisor and completed the appropriate Radiation Approval Application Form. |  |  |
| 4.2.3 Will any procedures cause a degree of discomfort, harassment, invasion of privacy, risk of physical injury, threat to dignity of participants or be otherwise potentially harmful to participants (NS Chapter 2.1)?  |  |  |
| 4.2.3.1 If **YES**, please provide further details:*Recommended length: 1 – 2 sentences describing the risk associated with a procedure.* |
| 4.2.4 Please list any of the potential burdens / risks to participants and their respective management strategies:*Please use short statements to describe potential burden / risk, and 1 – 2 short sentences stating the associated management strategy.* |
| Potential Burden / Risk | Management Strategy |
| 1. |  |  |
| 2. |  |  |
| 3. |  |  |
| 4. |  |  |
| 5. |  |  |
| 6. |  |  |

*\*If applicable, please obtain and attach your Radiation Approval Application Form to this submission and mark this in the Attachments Checklist.*

*\*Ensure that all procedures and risks are fully described in the “informed consent” form(s) (NS Chapter 2.2 and Chapter 2.3)*

*\*For section 4.2.4, please add lines if necessary, or delete lines that are not used.*

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| **4.3 Data Analysis** | **Yes** | **No** | **N/A** |
| 4.3.1 Sample Size*Please describe and justify the projected sample size. Please also include all key components of the sample size calculation, including the effect size, power and Type I error rate*. | 4.3.1.1 Projected number of participants:4.3.1.2 Details of the sample size calculation:4.3.1.3 Sample size justification*Recommended length: 2 – 4 short sentences.* |
| 4.3.2 Statistical Methods*Please define all outcomes, exposures, predictors, potential confounders and effect modifiers.**Please explain the statistical methods, including where applicable: handling of missing data, statistical assumptions, significance level, and multiple comparison corrections. If applicable, explain how loss to follow-up will be addressed, describe any sensitivity analysis. Describe the software that will be used.**For matched studies, give matching criteria and number of exposed and unexposed* | *Recommended length: 1 – 3 short sentences per point.*4.3.2.1 Clearly define all outcomes, exposures, predictors, potential confounders and effect modifiers (please including variable types, i.e., continuous or categorical). 4.3.2.2 Statistical tests / models that will be used:4.3.2.3 Handling of missing data:4.3.2.4 Significance level (please justify if not choose α=0.05):4.3.2.5 Multiple comparison corrections (if applicable):4.3.2.6 Sensitivity analysis (if applicable):4.3.2.7 Describe any efforts to address potential sources of bias:4.3.2.8 Software and packages:  |
| 4.3.3 Please explain how the procedures (statistical tests / models) link with the research objectives:*Recommended length: 1 – 2 short sentences.* |
| 4.3.4 Are any parts of the statistical procedures likely to be considered novel or sophisticated for this project? |  |  |  |
| 4.3.4.1 If **YES**, please explain how the statistical procedures are novel or sophisticated, and provide references where the statistical procedures have been previously developed: *Recommended length: 1 – 2 short sentences.* |
| 4.3.5 Have your statistical methods been reviewed and endorsed by a statistician? |  |  |  |
| 4.3.5.1 If **YES**, please provide the statistician’s details, including their **name and position**, **organisation** and **qualification**, accreditation and experience:*Recommended length: 1 – 2 short sentences.*Name / position:Organisation:Relevant qualification and/or accreditation:Relevant experience: |
| 4.3.5.2 If **NO**, or **not applicable**, please explain why:*Recommended length: 1 – 2 short sentences.* |
| 4.3.6 Qualitative Data Analysis Methods*Please explain the qualitative data analysis methods/procedures, including, where appropriate, underpinning theories and the software that will be used.* | *Recommended length: 2 – 6 short sentences.* |
| 4.3.6.1 Please explain how the qualitative data analysis procedures link with the research objectives:*Recommended length: 1 – 2 short sentences.* |

*\*Ensure that a suitably qualified statistician has been engaged in the study and is willing to endorse that the statistical methodology is appropriate for the study.*

*If applicable, please mark this section as ‘Yes’ in the Attachment Checklist (page 2) and ensure the endorsement section at the end of this form is completed. If not applicable, please provide a reason why (4.3.5.2).*

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| **5. Responsible Research Practice (Refer to** [**The Australian Code for the Responsible Conduct of Research)**](https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018) |
| **5.1 Stakeholder engagement and knowledge synthesis** |
| 5.1.1 Were stakeholders involved in the formulation of the research question? Please explain.5.1.2 Does the research question(s) link to current strategy, policy or practice? If yes, please provide details.5.1.3 Has a knowledge synthesis been undertaken? Or is there an existing knowledge synthesis that underpins the proposed study? Please describe. | *Recommended length: 1 – 2 sentences* |
| **5.2 Transparency and Open Science** |
| 5.2.1 Preregistration*Preregistration is a process whereby the research questions and analysis plan are defined and shared publicly before observing the research outcomes.**Please provide details of the plan for study preregistration, conditional on ethical approval, including where the study will be preregistered (e.g., Open Science Framework).* | *Recommended length: 1 – 2 sentences* |
| 5.2.2 Open protocol and open materials*Please provide details of the plan to share a study protocol or relevant study materials.* | *Recommended length: 1 – 2 sentences* |
| 5.2.3 Open data and analytical materials*Please provide details of your plan to share your data and analytical materials (e.g., computer generated code).* | *Recommended length: 1 – 2 sentences* |
| 5.2.4 Dissemination*Please provide details of your plan to post any report, article or manuscript produced on a preprint server.* |  |
| **5.3 Other responsible research practices** | **Yes** | **No** |
| 5.3.1 Quality Assurance of Data |  |  |
| 5.3.2 Use of Reporting Guidelines*A list of reporting guidelines can be found on the Enhancing the quality and transparency of health research (EQUATOR) Network (*[*https://www.equator-network.org/)*](https://www.equator-network.org/%29) |  |  |

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| **6. Project Time-frames** |  |  |
| 6.1 Planned timeframes (NS Chapter 3.1) | Month | Year |
|  Design |  |  |
|  Ethics |  |  |
|  Recruitment |  |  |
|  Commencement |  |  |
|  Data Analysis |  |  |
|  Report |  |  |
|  Project completion |  |  |
| 6.2 Give estimates for: |
|  Total average time required for participation (in hours) |  |
| The total number of questions if questionnaires or written tests are involved |  |

*\*Please note that ethics approval is valid for 3 months after the proposed completion date unless otherwise stated. Request to the Ethics Committee via the Secretary will be required for an extension.*

*\*Project activities may not be undertaken until formal written notification of final ethics approval has been provided.*

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| **7. Limited Disclosure (NS Chapters 2.3.1 - 2.3.4)** | **Yes** | **No** |
| 7.1 Does this proposal involve procedures specifically designed to directly modify the knowledge, thinking, attitudes, feelings or other aspects of the behaviour of participants? |  |  |
| 7.2 Does this study involve giving false/misleading information to participants? |  |  |
| 7.3 Does this study involve concealing information from participants? |  |  |
| 7.4 If **YES** to any of the above, please provide details and explain why this is necessary: |

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| --- | --- | --- |
| **8.2 Clinical Trial Registration** | **Yes** | **No** |
| 8.2.1 Does your research involve prospectively assigning human participants to one or more health-related interventions, or involve:• Experimental drugs• Cells and other biological products• Vaccines• Medical devices• Surgical procedures * Other medical treatments or procedures

• Psychotherapeutic and behavioural therapies• Health service changes• Preventive care strategies• Educational interventions * Diagnostic or screening test evaluations
 |  |  |
| 8.2.1.1 If **YES** to any of the above, has the project been provisionally registered with the Australian New Zealand Clinical Trials Registry (ANZCTR)?*Please refer to the Australian New Zealand Clinical Trials Registry (ANZCTR) website – Appendix 2a* |  |  |
| 8.2.1.1.1 Provisional clinical trial registration number: *Please note that once ethics approval is granted the ANZCTR record must be updated to a full registration.* |
| 8.2.1.1.2 If you have not provisionally registered your project as a clinical trial, please explain why registration was not required: |

*\*Applications that fulfil the criteria specified by the Australian New Zealand Clinical Trials Registry (ANZCTR)*, *must be provisionally registered prior to submission to the AIS Ethics Committee. Please note that ANZCTR also accepts observational studies for registration. More information is found at the links in Appendix 2a.*

*\*Where the study involves biomedical procedures, endorsement must be obtained from a Medical Officer who is independent of the research team. Please mark this section of the Attachment Checklist if applicable and ensure the endorsement section at the end of this form is completed.*

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| **9. Supplement Considerations**  | **Yes** | **No** |
| 9.1 Does the project involve supplements? |  |  |
| 9.2 Does the project involve use of medications? |  |  |
| 9.2.1 If **YES** to either of the above, please provide information on the supplement or medication being used:*Please list the supplement(s) being used and state the intended effect(s) in 1 – 2 sentences, as well as any other relevant information*. |
| **If YES to 9.1 or 9.2:** |
| 9.3 Have you provided links and information on the product in the Informed Consent Form(s)? |  |  |
| 9.4 Does the project comply with the AIS Supplements Policy (Appendix 8a)?  |  |  |
| 9.5 Has the supplement been tested by an independent third party for safety?*(e.g. Informed Sport, HASTA, etc.)* |  |  |
| 9.5.1 If **YES**, please attach a copy of the test results page and provide the following information:  |
| Third-party testing organisation | Batch / Reference Number |
|  |  |
| 9.5.2 If **NO**, please state why independent testing is not required:  |
| 9.6 Is the product TGA approved? |  |  |
| 9.6.1 If **NO**, is it approved by an equivalent body?  |  |  |
| 9.6.1.1 If **YES**, please provide details: |
| 9.7 Is the supplement or medication administered via injection? |  |  |
| 9.7.1 Does the project comply with the AIS Injection Policy (Appendix 8b)? |  |  |

*\*If applicable, please provide independent supplement test results as an attachment to this submission.*

*\*If the project does involve use of any administered substance (including supplements or medication) please obtain endorsement from an independent medical officer.*

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| **10. Laboratory Technician Checklist** | **Yes** | **No** |
| 10.1 Does your project involve the use of equipment for testing purposes? |  |  |
| **If YES to 10.1:** |
| 10.2 Please list the equipment to be used in the testing protocol (NS Chapter 5.3): |
| Equipment / item | Equipment owner (organisation) |
| 1. |  |  |
| 2. |  |  |
| 3. |  |  |
| 4. |  |  |
| 5. |  |  |
| 6. |  |  |
| 7. |  |  |
| 10.3 Is this equipment used throughout the methodology considered new or innovative? |  |  |
| 10.4 Have the listed equipment items recently been calibrated? |  |  |
| 10.4.1 If **YES** what was the calibration date? | DD/MM/YYYY |
| 10.4.2 Briefly state the calibration method for each item: |
| 10.5 Have the listed equipment items been validated? |  |  |
| 10.5.1 If **NO,** will this equipment be validated prior to the research being conducted? |  |  |
| 10.5.1.1 If **YES,** state when validation will occur in the context of the project timeframes (Section 6) and explain how validation will be carried out: |
| 10.5.2 Can you provide equipment logbook information for maintenance and calibration if requested by the AIS Ethics Committee? |  |  |
| 10.6 Has all equipment with connection to mains power been safety tested and tagged? |  |  |

*\*For section 10.2, please add lines if necessary, or delete lines that are not used.*

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| **11. Participants****11.1 Description of Participants** |
| 11.1.1 Sport(s) |  |
| 11.1.2 Age Range |  |
| 11.1.3 Institutions involved |  |
| 11.1.4 Athletic Status(elite, sub-elite, novice, recreational, sedentary) |  |
| 11.1.5 Please provide a summary description of your participant population:*Recommended length: 1 – 2 short sentences* |
|  | **Yes** | **No** |
| 11.1.6 Are you seeking to collect sex and/or gender information from participants? |  |  |
| 11.1.6.1 If YES, please justify why this information is required*Please refer to the Australian Government Guidelines (Appendix 10a).* |
| 11.1.7 Criteria for participation |
| 11.1.7.1 Inclusion: |  |
| 11.1.7.2 Exclusion: |  |

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| **11.2 Specific Populations (NS Section 4)** | **Yes** | **No** |
| 11.2.1 Does the project involve, or is there a possibility that the project could involve, participants who: |
|  Are in receipt of dAIS funding?  |  |  |
| Have an intellectual impairment (NS 4.5)?  |  |  |
| Have a mental illness? (NS 4.5) |  |  |
|  Have a physical impairment (NS 4)?  |  |  |
| Are highly dependent on medical care? (NS 4.4) |  |  |
|  Are minors (<18yrs) (NS 4.2)? |  |  |
|  Are Aboriginal or Torres Straight Islanders (NS 4.7)?  |  |  |
| Do not speak English as their primary language, or at all?  |  |  |
| Are members of a socially identifiable group with special cultural or religious needs or political vulnerabilities? |  |  |
| May be involved in illegal activities (NS 4.6)? |  |  |
| Are pregnant? (NS 4.1) |  |  |
| 11.2.1.1 Does the project involve human foetuses or foetal tissue? (NS 4.1) |  |  |
| 11.2.2 If **YES** to any of the above, how are the specific ethical considerations being addressed? *Recommended length: 2 – 3 sentences per specific participant type.* |
| 11.2.3 Is translation of any research material for participants required? |  |  |
| 11.2.3.1 If **YES**, who is responsible for this translation?  |
| 11.2.4 If applicable, please provide your working with vulnerable people ID number:  |

*\*Please attach any translated study material in addition to the same material written in English.*

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| **11.3 Consent and Recruitment** | **Yes** | **No** |
| 11.3.1 Through which of the following are you seeking consent, including consent for the prospective or retrospective use of data: *Please refer to the NHMRC National Statement for further information on the types of consent (*[*National Statement on Ethical Conduct in Human Research 2023 | NHMRC*](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023#block-views-block-file-attachments-content-block-1)*)* |
| Informed Consent (NS Chapters 2.2 and 2.3) |  |  |
| 11.3.1.1 If you are **not** seeking informed consent, explain why not:*Recommended length: 2 – 3 sentences* |
| Opt Out Consent (NS Chapters 2.3.5 – 2.3.8) |  |  |
| 11.3.1.2 Ifyou are seeking opt-out consent, explain why: *Recommended length: 2 – 3 sentences* |
| Consent Waiver (NS Chapter 2.3.9-2.3.12) |  |  |
| 11.3.1.3 If you are seeking a consent waiver from the EC, explain why (- please refer to the National Statement in your answer):*Recommended length: 3 – 4 sentences* |

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| **11.4 Participant Recruitment** |  **Yes** | **No** |
| 11.4.1 Are you recruiting participants for active participation in this study? |  |  |
| 11.4.2 Are you recruiting participants in order to use their data in this study? |  |  |
| **If YES to 11.4.1 or 11.4.2:** |
| 11.4.3 Which of the following methods will you use to recruit participants: |
| E-mail  |  |  |
| Word of mouth  |  |  |
| Referral  |  |  |
| Direct correspondence with a team or coach  |  |  |
| 11.4.3.1 Other – please elaborate:*Recommended length: 1 – 2 short sentences* |
| 11.4.4 Please provide a detailed description of how each participant type / group will be contacted and recruited.*Outline a step-by-step process using short sentences.* |
| 11.4.5 Please describe how you will obtain approval to access participants and their contact details:*Recommended length: 2 – 3 statements on how approval will be sought and from whom.* |
| 11.4.6 Is organisation approval required prior to recruitment? |  |  |
| 11.4.6.1 If **YES**, provide details of how organisation approval will be sought:*State who will be approached for approval and how they will be contacted. Please provide a written or verbal script for this interaction as an attachment to this submission.* |
| 11.4.7 Will participants receive any monetary or other benefits for their participation (NS 2.2.11)? |  |  |
| 11.4.7.1 If **YES**, please provide further detail:*Recommended length: 1 – 2 sentences.* |

*\*Please include a copy of all written or verbal recruitment scripts as attachments to this submission and mark the Attachments Checklist.*

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| **11.5 Participant Follow-up and Support** | **Yes** | **No** |
| 11.5.1 Are there processes in place for participant follow up if any results yielded are abnormal or adverse?  |  |  |
| 11.5.1.1 Please explain your response to 11.5.1:*Recommended length: 2 – 3 sentences.* |
| 11.5.2 Will any feedback be provided to participants about the results of the research?  |  |  |
| 11.5.2.1 If **YES**, please explain how feedback will be provided:*Recommended length: 1 – 2 sentences.* |
| 11.5.3 Please explain how you will provide support/counselling to participants. Please include the counselling service that will be made available: *Recommended length: 2 – 4 sentences.* |

*\*Please ensure any opportunities or requirements for providing feedback or follow-up are detailed in the Information to Participants sheet.*

|  |  |  |
| --- | --- | --- |
| **11.6 Location** | **Yes** | **No** |
| 11.6.1 Where will each component of the research be conducted? |
| 11.6.2 Is research being conducted overseas? |  |  |
| 11.6.2.1 If **YES**, are there any mandatory ethics approval processes to be undertaken in the country (countries) where research will be conducted? |  |  |
| 11.6.2.1.1 If **NO**, please provide evidence to confirm this.*Written correspondence or documentation confirming that no ethics approval is required and may be attached to this submission.* |
| 11.6.2.1.2 If **YES**, please summarise the principles of the applicable ethics approval process or provide direction (links or documentation) to the designated ethics approval committee resources. |

|  |  |  |
| --- | --- | --- |
| **12. Data Management****12.1 Data Types** | **Yes** | **No** |
| 12.1.1 Please describe the data that will be collected:*Recommended length: list all data types to be used* |
| 12.1.2 Will any of the following data types be collected?*Please see definitions of data as listed under the Privacy Act (Appendix 11a)* |
| Personal Information |  |  |
| Sensitive Personal Information |  |  |
| Health information |  |  |
| Non-personal information |  |  |
| 12.1.2.1 If sensitive and/or health information will be collected, please provide further details about the type of information:*Recommended length: 1 – 2 sentences per data type to be collected.* |

|  |  |  |
| --- | --- | --- |
| **12.2 Privacy and Security** | **Yes** | **No** |
| 12.2.1 Have you consulted with your organisation’s Privacy, IT or data management advisory staff to ensure the security and privacy of your data according to the Australian Privacy Principles (APP11)? |  |  |
| 12.2.2 Are you seeking approval to analyse retrospective data?  |  |  |
| 12.2.2.1 If **YES**, what is the data source?  |
| 12.2.2.2 How will you gain access to existing records in a way that will not infringe privacy requirements (NS 2.3)?*Recommended length: 3 – 4 sentences* |
|  | **Yes** | **No** |
| 12.2.3 Does your data require collection of any of the following: |
| Names |  |  |
| Email Address |  |  |
| Dates (other than year) |  |  |
| Phone numbers |  |  |
| Health Insurance Number |  |  |
| Medicare Number |  |  |
| Device identifiers or serial numbers |  |  |
| Biometric Identifiers |  |  |
| Account numbers |  |  |
| Medical record numbers |  |  |
| Sport & classification that may identify an individual |  |  |
| Geographical Identifiers |  |  |
| Photographic images |  |  |
| Video recording |  |  |
| Audio recording |  |  |
| Any other unique identifying number, characteristics or code |  |  |
| 12.2.3.1 Other identifiers – please list: |
| 12.2.3.2 If any of the categories in 12.2.3 apply, describe how you will maintain the anonymity of participants *(NS Element 4 (page 32 and 3.1.39 – 3.1.71):**Recommended length: 3 – 4 sentences* |
| 12.2.3.3 If none of the categories in 12.2.3 apply, will the data be re-identifiable in any way?*(i.e. coded in some way that only the research team can connect the data to specific participants)* |  |  |
| 12.2.3.3.1 If data will be re-identifiable please outline in more detail how the information will be coded:*Please note that if there is a risk that the data may be re-identifiable you may require written informed consent.**Recommended length: 3 – 4 sentences* |
|  | **Yes** | **No** |
| 12.2.4 Does your project involve case studies (either of a single participant, or of multiple participants)? *If case study descriptions are to be written at any stage, please ensure that the Information Sheet for participants indicates that participants will likely be identifiable.* |  |  |

|  |  |  |
| --- | --- | --- |
| **12.3 Data Access and Storage** | **Yes** | **No** |
| 12.3.1 Which organisation(s) will own the data collected in this project? |  |
| 12.3.2 Will the following people have access to the data? |
| Researchers and / or supervisors listed in the application |  |  |
| Research assistants listed in this application |  |  |
| Parties other than those listed in this application |  |  |
| 12.3.2.1 Please explain which data will be accessed, by whom, and why:*Recommended length: 1 – 2 sentences per party.* |
| 12.3.3 Who will perform the data analysis? |
| 12.3.3.1 If the person / people performing data analysis is / are external to the research team, please provide their details: |
| Name | Organisation | Qualifications |
| 1. |  |  |
| 2. |  |  |
| 3. |  |  |
| 12.3.4 Where will each data type be stored? *Recommended length: 2 – 3 short sentences.*  |
| 12.3.5 If the data will not be stored on Australian Sports Commission systems, what security measures are in place to ensure security and compliance with relevant legislation?*For example: describe the systems in place to assure against misuse, interference, loss, unauthorised access, unauthorised modification and unauthorised disclosure.**Please list all measures.* |
| 12.3.6 If you are not using Australian Sports Commission systems, what are your data storage backup measures?*Please list all measures.* |
| 12.3.7 How will you transmit data (if required) within the research team?*Recommended length: 1 – 2 short statements.* |
|  | **Yes** | **No** |
| 12.3.8 Do you anticipate using the data from this study for future work/projects?*If data will be used in future work, ensure this is included in the information to participants.* |  |  |
| 12.3.8.1 If **YES**, please explain:*Recommended length: 3 – 4 sentences.* |
| 12.3.9 For what length of time will the data be retained, and why?*e.g. At least 12 months, 5 years, etc. Please refer to the Commonwealth Data Retention Guidelines in Appendix 11c.* |
| 12.3.10 Have you considered risk in relation to data, and does your assessment of risk fall within the acceptable risk appetite of your organisation?*For ASC staff, the Risk Management Framework and ASC risk appetite information can be found in Appendix 11d*. |  |  |
| 12.3.11 Do you require permission from a data custodian to access data?  |  |  |
| **If YES to 12.3.11:** |
| 12.3.11.1 Please provide a signed letter, from an authorised data custodian, granting permission to access the data. *Refer to the authorised persons definition in Appendix 11b.* |
| 12.3.12 Please provide details of the authorised data custodian: |
| Name | Organisation | Contact Details (Phone or email) |
|  |  |  |

|  |  |  |
| --- | --- | --- |
| **13. Budget** | **Yes** | **No** |
| 13.1 Is the project funded? |  |  |
| 13.1.1 If **YES**, please attach written proof of funding approval to this submission. |
| 13.2 Budget required | $ |
| 13.3 Approved level of funding | $ |
| 13.4 Source(s) of funding |  |
| 13.5 Is there commercial interest in the project? |  |  |
| 13.5.1 If **YES**, has the commercial company involved been made aware of any publishing of results? *(NHMRC Code of Conduct 3.1.68)* |  |  |
| 13.6 Are there any ethical considerations related to funding this research? *e.g. Personal or other interest or investment in the outcomes of the study.* |  |  |
| 13.6.1 Please elaborate:*Recommended length: 2 – 3 sentences per consideration.* |

**Information to Participants**

**Research Title:**

**Principal Researcher:**

[your name and organisation] [your contact details including phone/mobile and email]

We would like to invite you to participate in this [original/undergraduate/postgraduate] research project. You should only participate if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

**Aim:**

The aim of this research project is to [brief description].

**Benefits:**

This study will provide [brief outline of expected benefits].

**What is involved?**

[Outline what will be involved – who, where and when]

**Supplements/Medication use (use where appropriate)**

[Outline the name of the supplement / medication – include links to product information sheets]

[State that the use of the supplement / medication used complied with the AIS policies and insert a link to the AIS supplement policy and AIS injections policy where appropriate]

[Insert supplement/medication name followed by the following paragraph “Is not prohibited under the WADA 2024 Prohibited list. However, if you have any concerns about the status or use of this substance or method, please raise these concerns with the principal researcher or AIS Ethics Committee Secretary. Alternatively, you may wish to check the substance yourself: For medications visit: [globaldro.com](https://www.globaldro.com/Home), for supplements use the Supplement Checker on the [Sport Integrity Australia App](https://www.sportintegrity.gov.au/resources/sport-integrity-apps-and-vr)]

[Note that the substance is in pure form and has been checked to ensure it is not contaminated, and include information as evidence to support this statement]

[Note that the supplement / medicine is approved by the Therapeutic Goods Administration (TGA)]

**Who are we recruiting?**

[Explain about who you are recruiting for your study (including exclusion criteria)]

**Adverse Effects and Withdrawal:**

[Explain any adverse effects and state that they have the right to withdraw without any disadvantage. Include measures of follow up should results yield any concerning or abnormal results]

**Confidentiality:**

[Explain how all data will be kept confidential and be stored, who will see it, and how it will be issued, for example, published in an article or presented at a conference. Reassure participants that they will not be identifiable. Include how and when participants will have access to their results]

**Ethics Approval:**

[Explain that your study has been approved by the Australian Institute of Sport Ethics Committee]

**Further information:**

[Remember to state that participants can contact the principal researcher if they require any further information relating to any aspect of participating in the study.]

**Concerns and Complaints:**

If you have any concerns or complaints with respect to the conduct of this study, you may contact the Secretary of the AIS Ethics Committee by email to ethics@ausport.gov.au, by phone on (02) 6214 7884, or by mail to The Secretary AIS Ethics Committee PO Box 176 Belconnen ACT 2616.

**‘INFORMED CONSENT’ FORM (Minor)**

Project Title:

Principal Researchers:

I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (*participant*) agree to participate as a volunteer in a research project as an authorised part of the research program of the Australian Sports Commission under the supervision of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (*supervisor*).

The investigation and my part in the investigation have been fully explained to me by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (*recruiter/researcher*) and I understand the explanation. A copy of the procedures of this investigation and a description of any risks and discomforts has been provided to me and has been discussed in detail with me.

* I have been given an opportunity to ask any questions I have had, and all such questions and enquiries have been answered to my satisfaction.

* I understand that I am free to refuse any items or to answer questions in interviews or questionnaires.

* I understand that I am free to end my participation in the project or activity at any time, without consequences to myself.

* I understand that where possible, I am free to withdraw my information without consequences to myself.

* I understand that I continue to own my information and have rights to access and seek correction of my information.
* I understand that any information or answers I give to questions will remain confidential and not reveal my identity.

* I agree that to the best of my knowledge, I have no physical or mental illness or weakness that would increase the risk to me of being part of this investigation.

* I am participating in this project of my own free will and I have not been forced in any way to participate.

* I have read and understand the product and policy information provided to me on the use of supplements/medications within the study (where applicable)

***Privacy Statement****: The information submitted will be managed in accordance with the Privacy Act 1988.*

**For the participant:**

​​☐​I have read and understand the information on this form and *consent to [insert organisation] collecting, holding and using my personal and health information for the purposes of this research project.*

Signature of Participant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_/\_\_\_/\_\_\_

**For the parent /guardian:**

​​☐​ I consent to my child’s participation in the research project in accordance with the terms and information outlined above.

Signature of Parent or

Guardian of minor: (under 18 years) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_/\_\_\_/\_\_\_

I, the undersigned, was present when the study was explained to the participant(s) in detail and to the best of my knowledge and belief it was understood.

Signature of Principal Researcher: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_/\_\_\_/\_\_\_

**‘INFORMED CONSENT’ FORM (Adult)**

Project Title:

Principal Researchers:

This is to certify that I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (*participant*) hereby agree to participate as a volunteer in a research project as an authorised part of the research program of the Australian Sports Commission under the supervision of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (*supervisor*).

The investigation and my part in the investigation have been defined and fully explained to me by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (*recruiter/researcher*) and I understand the explanation. A copy of the procedures of this investigation and a description of any risks and discomforts has been provided to me and has been discussed in detail with me.

* I have been given an opportunity to ask whatever questions I may have had, and all such questions and enquiries have been answered to my satisfaction.
* I understand that I am free to deny any answers to specific items or questions in interviews or questionnaires.
* I understand that I am free to withdraw consent and to discontinue participation in the project or activity at any time, without disadvantage to myself.
* I understand that I continue to own my information and have rights to access and seek correction of my information.
* I understand that, where possible, I am free to withdraw my data from analysis without disadvantage to myself.
* I understand that any data or answers to questions will remain confidential with regard to my identity.
* I certify to the best of my knowledge and belief, I have no physical or mental illness or weakness that would increase the risk to me of participating in this investigation.
* I am participating in this project of my own free will and I have not been coerced in any way to participate.
* I have read and understand the product and policy information provided to me on the use of supplements/medications within the study (where applicable)

***Privacy Statement****: The information submitted will be managed in accordance with the Privacy Act 1988.*

[ ]  *I consent to the [insert organisation]*

*collecting, holding and using my personal and health information for the purposes of this research project.*

Signature of Participant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_/\_\_\_/\_\_\_

I, the undersigned, was present when the study was explained to the participant(s) in detail and to the best of my knowledge and belief it was understood.

Signature of Principal Researcher: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_/\_\_\_/\_\_\_

**‘INFORMED CONSENT’ FORM (Organisation)**

Project Title:

Principal Researchers:

This is to certify that I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (*organisation representative*) hereby agree that participants affiliated with (*organisation*) may volunteer to participate in a research project as an authorised part of the research program of the Australian Sports Commission under the supervision of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (*supervisor*).

The investigation and requirements for participants have been defined and fully explained to me by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (*recruiter/researcher)* and I understand the explanation. A copy of the procedures of this investigation and a description of any risks and discomforts has been provided to me and has been discussed in detail with me.

* I have read and understand the informed consent forms provided to participants and / or their parent / guardian.
* I have been given an opportunity to ask whatever questions I may have had, and all such questions and enquiries have been answered to my satisfaction.
* I understand that participants from (*organisation*) are free to deny any answers to specific items or questions in interviews or questionnaires.
* I understand that participants from (*organisation)* are free to withdraw consent and to discontinue participation in the project or activity at any time, without disadvantage.
* I understand that, where possible, participants from (*organisation*) are free to withdraw their data from analysis without disadvantage.
* I understand that any data or answers to questions will remain confidential with regard to participant identity.
* Participants in this project are participating of their own free will and have not been coerced in any way to participate.
* I have read and understand the product and policy information provided on the use of supplements/medications within the study (where applicable)

***Privacy Statement****: The information submitted will be managed in accordance with the Privacy Act 1988.*

[ ] I acknowledge that I have read the submission and am satisfied that the area of research is supported by our organisation.

Print name: ……………………………………………………………

Sign: ……………………………………… / /

I, the undersigned, was present when the study was explained to the organisational representative in detail and to the best of my knowledge and belief it was understood.

Signature of Principal Researcher: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_/\_\_\_/\_\_\_

**Australian Privacy Principles**

[The Australian Privacy Principles](https://www.oaic.gov.au/privacy/australian-privacy-principles) (APPs) are the foundation of the privacy protection framework in the *Privacy Act 1988*. They are principles-based laws that set out the standards, rights, and obligations for handling personal information.

**Principle 1 — open and transparent management of personal information**

An APP entity must ensure it manages personal information in an open and transparent way and take reasonable steps to implement practices, procedures and systems that will ensure the entity complies with the Australian Privacy Principles and any [￼ ￼registered APP code](https://www.oaic.gov.au/privacy/privacy-registers/privacy-codes/privacy-codes-register).

All personal information and data collected on athletes through research is managed by the Australian Sports Commission under the ASC Information and Records Management policy and ASC Privacy Policy.

**Principle 2 — anonymity and pseudonymity**

Individuals must have the option of not identifying themselves, or of using a pseudonym, when dealing with an APP entity in relation to a particular matter. This does not apply if, in relation to that matter: the AP  entity is required or authorised by or under an Australian law, or a court/tribunal order, to deal with individuals who have identified themselves; or it is impracticable for the APP entity to deal with individuals who have not identified themselves or who have used a pseudonym.

**Principle 3 — collection of solicited personal information**

An APP entity may only solicit and collect personal information that is reasonably necessary for, or directly related to, one or more of its functions or activities. An APP entity may only solicit or collect sensitive information if the individual consents to the sensitive information being collected, unless an exemption applies. An APP entity must solicit and collect personal information only by lawful means and directly from the individual, unless an exemption applies. or impracticable to do so.

**Principle 4 — dealing with unsolicited personal information**

Unsolicited personal information is personal information received by an APP entity where the entity has taken no active steps to collect the information. If an APP entity receives unsolicited personal information, it must decide whether it could have collected the information under APP 3 (collection of solicited personal information). Unsolicited personal information that could not have been collected under APP 3, must be destroyed or de-identified as soon as practicable if it is lawful and reasonable to do so.

**Principle 5 — notification of the collection of personal information**

An APP entity that collects personal information about an individual is required to take reasonable steps to notify the individual of certain matters or to ensure the individual is aware of those matters such as collecting the personal information from someone other than the individual, or if the collection of the personal information is required or authorised by or under an Australian law or a court/tribunal order.

**Principle 6 — use or disclosure of personal information**

An APP entity that holds personal information about an individual can only use or disclose the information for a particular purpose (the primary purpose), for which it was collected. The entity must not use or disclose the information for another purpose (the secondary purpose) unless the individual has consented to the use or disclosure of the information, or an exemption applies.

**Principle 7 — direct marketing**

An organisation must not use or disclose personal information for the purpose of direct marketing. Where an organisation is permitted to use or disclose personal information for the purpose of direct marketing, it must always:

* + allow an individual to request not to receive direct marketing communications (opting out), and
	+ comply with that request.

**Principle 8 — cross-border disclosure of personal information**

Before an APP entity discloses personal information about an individual to an overseas recipient, the entity must take such steps to ensure that the overseas recipient does not breach the Australian Privacy Principles in relation to the information. An APP entity that discloses personal information to an overseas recipient is accountable for any acts or practices of the overseas recipient in relation to the information that would breach the APPs.

**Principle 9 — adoption, use or disclosure of government related identifiers**

An organisation must not adopt a government related identifier unless an exemption applies. The objective of this principle is to restrict general use of government related identifiers by organisations so that they do not become universal identifiers. This could jeopardise privacy by enabling personal information from different sources to be matched and linked in ways that an individual may not agree with or expect.

**Principle 10 — quality of personal information**

An APP entity must take reasonable to ensure that the personal information it collects is accurate, up-to-date and complete.

An APP entity must also take reasonable steps to ensure that the personal information it uses or discloses is, having regard to the purpose of the use or disclosure, accurate, up-to-date, complete and relevant.

**Principle 11 — security of personal information**

An APP entity that holds personal information must take reasonable steps to protect the information from misuse, interference and loss; as well as unauthorised access, modification or disclosure.

An APP entity must take reasonable steps to destroy or de-identify the personal information it holds once the personal information is no longer needed for any purpose for which the personal information may be used or disclosed under the privacy principles.

**Principle 12 — access to personal information**

An APP entity that holds personal information about an individual must, on request give the individual access to the information. This principle also sets out minimum access requirements, including the time period for responding to an access request, how access is to be given, and that a written notice, including the reasons for the refusal, must be given to the individual if access is refused. The principle also operates alongside and does not replace other informal or legal procedures by which an individual can be given access to information, for example, the FOI Act. information.

**Principle 13 — correction of personal information**

An APP entity must take reasonable steps to correct personal information it holds, to ensure it is accurate, up-to-date, complete, relevant and not misleading, having regard to the purpose for which it is held. This requirement applies where the APP entity is satisfied the personal information is inaccurate, out-of-date, incomplete, irrelevant or misleading; or the individual requests the entity to correct the personal information.

I, ………………………………… (the undersigned), acknowledge the Australian Privacy Principles and undertake to ensure that these principles are adhered to with reference to collection of data from persons, for the purpose of this research project.

Signature of Principal Researcher: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_/\_\_\_/\_\_\_**Endorsements**

**Medical Officer Endorsement**

*\*Where the study involves biomedical procedures, please obtain endorsement from a medical officer who is independent of the research team.*

I acknowledge that I have thoroughly read the submission and am satisfied that the biomedical procedures meet the appropriate medical standards, have sufficient rigour and that the research team has the appropriate resources and expertise to perform the study.

Print name:

Sign: Date: \_\_\_/\_\_\_/\_\_\_

Organisation:

Position:

Qualifications:

###### **Statistician Endorsement**

###### *\*If applicable; please obtain endorsement from a statistician as per Section 4.3*

I acknowledge that I have read and discussed the statistical methods in the submission with the researcher involved. I am satisfied with the planned statistical approach and the rationale behind the sample size estimation. I am satisfied that the research team has the capability to undertake this statistical approach.

Print name:

Sign: Date: \_\_\_/\_\_\_/\_\_\_

###### **Principal Researcher**

Print name:

Sign: Date: \_\_\_/\_\_\_/\_\_\_

 Appendices

**2a** Australian New Zealand Clinical Trials Registry:

<http://www.anzctr.org.au/Faq.aspx#r1>

Australian Clinical Trials:

<https://www.australianclinicaltrials.gov.au/what-clinical-trial>

**8a** AIS Supplements Policy and information:

* AIS Webpage on Supplements:

<https://ais.gov.au/nutrition/supplements>

* The AIS Sports Supplement Framework:

<https://www.ais.gov.au/__data/assets/pdf_file/0014/1000841/Position-Statement-Supplements-and-Sports-Foods-abridged_v2.pdf>

**8b** AIS Injection Policy:

<https://www.sportaus.gov.au/__data/assets/pdf_file/0006/687624/AIS_No_Needles_Policy_-_November_2018.pdf>

**10a** Australian Government Guidelines on the Recognition of Sex and Gender:

<https://www.ag.gov.au/Publications/Documents/AustralianGovernmentGuidelinesontheRecognitionofSexandGender/AustralianGovernmentGuidelinesontheRecognitionofSexandGender.pdf>

**11a** Australian Government privacy and information type definitions:

Australian Privacy Act Definitions:

[*https://www.alrc.gov.au/publication/for-your-information-australian-privacy-law-and-practice-alrc-report-108/6-the-privacy-act-some-important-definitions/*](https://www.alrc.gov.au/publication/for-your-information-australian-privacy-law-and-practice-alrc-report-108/6-the-privacy-act-some-important-definitions/)

Definitions from the Office of the Australian Information Commissioner:

Health information:<https://www.oaic.gov.au/privacy/health-information/what-is-health-information/>

Personal Information and Sensitive personal Information: <https://www.oaic.gov.au/privacy/your-privacy-rights/your-personal-information/what-is-personal-information/>

**11b** Authorised person: someone who holds a position in the organisation and has been delegated by a CEO to act on their behalf. For example; Director of the department responsible for storing the data or permitting data access.

**11c** Commonwealth data retention guidelines:

Australian Sports Commission Records Authority 2014

<https://www.naa.gov.au/sites/default/files/2019-12/agency-ra-2014-00494830.pdf>

**11d** ASC risk management:

ASC Risk Management Framework:

[https://ausport.sharepoint.com/sites/intranet/SitePages/Risk-Management.aspx](https://aus01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fausport.sharepoint.com%2Fsites%2Fintranet%2FSitePages%2FRisk-Management.aspx&data=02%7C01%7CRikki.Belder%40ausport.gov.au%7C7860ec18d6c547e5350b08d838220911%7C8d2e0f4c55f24cb18ee7da5dd3ff3600%7C0%7C0%7C637321066118884381&sdata=Ns%2BLgqpmYnpa2KJuSA6a0i2akj0dHdC9zKE%2Fg6K9ZjQ%3D&reserved=0)

ASC Risk Appetite Statements:

[https://ausport.sharepoint.com/:w:/r/sites/intranet/\_layouts/15/Doc.aspx?sourcedoc=%7BE6385979-FE5E-422A-BDB2-FB845E2F740A%7D&file=SportAus%20Risk%20Appetite%20Statement.dotx&action=default&mobileredirect=true&DefaultItemOpen=1](https://ausport.sharepoint.com/%3Aw%3A/r/sites/intranet/_layouts/15/Doc.aspx?sourcedoc=%7BE6385979-FE5E-422A-BDB2-FB845E2F740A%7D&file=SportAus%20Risk%20Appetite%20Statement.dotx&action=default&mobileredirect=true&DefaultItemOpen=1)

For further information on Privacy, please contact the ASC Privacy Officer: privacy@ausport.gov.au

For all questions related to your submission please contact the AIS Ethics Committee Secretary: ethics@ausport.gov.au

Version updated 26th September 2024