**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) and National Sporting Organisations (NSOs) 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%5CUsers%5CKendrickJ%5CDownloads%5CNational-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).
* 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.

**Checklist for Submission of Application**

* Full details of the Principal Researcher have been provided.
* Application has been signed by the researcher(s) and supervisor(s).
* Starting date of the research postdates the EC meeting at which the application will be considered.
* The [relevant dates](https://ais.gov.au/research-submissions/ec#submission_dates) for receipt of applications has been noted.
* All questions have been answered and the language used can be understood by a layperson –any explanations can be understood by someone without technical knowledge.
* The submission has been checked for accuracy, scientific rigour and spelling / punctuation.
* Attachments are clearly identified, numbered and included with the application.
* Follow-up counselling has been identified if necessary, and the counselling service specified.
* The attachments checklist on Page 2 has been completed.
* The EC submission form is in **Microsoft Word Document** format.

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

|  |  |
| --- | --- |
| **Date of Submission** |  |
| **Research Submission ID** | *Field to be completed by Ethics Committee Secretary* |
| **Ethics Approval Number** |  |
| *Required for minor variations and resubmissions, please include original approval number followed by ‘\_R1’ for first revision or ‘\_R2’ for second revision.* |
| **Project Title** |  |
| **Plain Language Statement** | *Recommended length: 1 – 2 sentences* |
| *Please provide a plain language ‘title statement’ about the study that can be understood by a layperson.* |

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| **Attachment Checklist** | **Yes** | **No** |
| Endorsement by an **independent** **medical officer** |  |  |
| **Supplement or medication testing** documentation |  |  |
| All **questionnaires, surveys, interview questions and test items** |  |  |
| Endorsement by an appropriate **statistician** |  |  |
| **Radiation Approval Application** Form |  |  |
| 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) |  |  |
| ***Information to Participants*** information sheet |  |  |
| Participant **Informed Consent form** template |  |  |
| **Informed Consent (Organisation) form** template |  |  |
| Signed letter of permission to access data (Question 11.3.11 – 11.3.12) |  |  |
| Proof of approval for project funding |  |  |
| Any other relevant supporting documentation |  |  |

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

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| 1. **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.*

|  |  |  |
| --- | --- | --- |
| **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** | **Yes** | **No** |
| 1.4.1 Are there any actual or perceived conflicts of interest for the research team? |  |  |
| 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.* |

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| 1. **About the Project**

**Co-Researchers****Organisation(s)** |
| **2.1 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.* |
| 1. |  |
| 2. |  |
| 3. |  |
| 4. |  |
| 5. |  |

*\*For section 2.1, please add lines if necessary, or delete lines that are not used.*

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| **2.2 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 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 do not exceed the allocated space.*

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| **2.3 Background**  |

*\* The box is limited in size. Please do not exceed the allocated space – the box size should not be increased past the present page. Please include references at the bottom.*

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| Please include the statement of the problem, relevant literature and justification for the study: |

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| **3. Project Summary** |  **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 1.6)?*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? |  |  |
| 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 ExperimentalDesign*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.* *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, stating why they are reliable or whether they have been proven as valid or reliable.* |

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| **4.2 Statistical Procedures** | **Yes** | **No** |
| 4.2.1Statistical Procedures*Please explain the statistical procedures, including where appropriate: the descriptive approach, handling of missing values, statistical assumptions, significance level, multiple comparison corrections, covariate adjustment, and software packages.* |  |
| 4.2.2 Please explain how the procedures link with the research objectives: |  |
| 4.2.3 Are any parts of the statistical procedures likely to be considered novel or sophisticated for this project? |  |  |
| 4.2.3.1 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.* |
| 4.2.4 Have your statistical methods been reviewed and endorsed by a statistician? |  |  |
| 4.2.4.1 If **YES**, please provide the statistician’s details: |
| Name / Position | Organisation | Qualification(s) |
|  |  |  |
| 4.2.4.2 If **NO**, or **not applicable**, please explain why:*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 (4.2.4.2).*

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| **4.3 Location** | **Yes** | **No** |
| 4.3.1 Where will each component of the research be conducted? |
| 4.3.2 Is research being conducted overseas? |  |  |
| 4.3.2.1 If **YES**, are there any mandatory ethics approval processes to be undertaken in the country (countries) where research will be conducted? |  |  |
| 4.3.2.1.1 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.* |
| 4.3.2.1.2 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. |

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| **5. Project Time-frames** |  |  |
| 5.1 Planned timeframes (NS 3) | Month | Year |
|  Design |  |  |
|  Ethics |  |  |
|  Recruitment |  |  |
|  Commencement |  |  |
|  Data Analysis |  |  |
|  Report |  |  |
|  Project completion |  |  |
| 5.2 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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| **6. Blinding** | **Yes** | **No** |
| 6.1 Does this proposal involve procedures specifically designed to directly modify the knowledge, thinking, attitudes, feelings or other aspects of the behaviour of participants (NS 2.3)? |  |  |
| 6.2 Does this study involve giving false/misleading information to participants? |  |  |
| 6.3 Does this study involve concealing information from participants? |  |  |
| 6.4 If **YES** to any of the above, please provide details and explain why this is necessary: |

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| **7.1 Procedural** | **Yes** | **No** |
| 7.1.1 Are the procedures, or their combination, new or innovative (not established) (NS 3)? |  |  |
| 7.1.1.1 If **YES**, please explain which components are new or innovative: |
| 7.1.2 Will this study involve ionising radiation, non-ionising radiation or high intensity sound *(Including DXA)*? |  |  |
| 7.1.2.1 If **YES**, have you sought advice from a relevant Radiation Safety Advisor and completed the appropriate Radiation Approval Application Form. |  |  |
| 7.1.3 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 2.1)? |  |  |
| 7.1.3.1 If **YES**, please provide further details:*Recommended length: 1 – 2 sentences describing the risk associated with a procedure.* |
| 7.1.4 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 2.2 and 2.3)*

*\*For section 7.1.4, please add lines if necessary, or delete lines that are not used.*

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| **7.2 Clinical Trial Registration** | **Yes** | **No** |
| 7.2.1 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
 |  |  |
| 7.2.1.1 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* |  |  |
| 7.2.1.1.1 Provisional clinical trial registration number: *Please note that once ethics approval is granted the ANZCTR record must be updated to a full registration.* |
| 7.2.1.1.2 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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| **8. Supplement Considerations**  | **Yes** | **No** |
| 8.1 Does the project involve supplements? |  |  |
| 8.2 Does the project involve use of medications? |  |  |
| 8.2.1 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 8.1 or 8.2:** |
| 8.3 Have you provided links and information on the product in the Informed Consent Form(s)? |  |  |
| 8.4 Does the project comply with the AIS Supplements Policy (Appendix 8a)?  |  |  |
| 8.5 Has the supplement been tested by an independent third party for safety?*(e.g. Informed Sport, HASTA, etc.)* |  |  |
| 8.5.1 If **YES**, please attach a copy of the test results page and provide the following information:  |
| Third-party testing organisation | Batch / Reference Number |
|  |  |
| 8.5.2 If **NO**, please state why independent testing is not required:  |
| 8.6 Is the product TGA approved? |  |  |
| 8.6.1 If **NO**, is it approved by an equivalent body?  |  |  |
| 8.6.1.1 If **YES**, please provide details: |
| 8.7 Is the supplement or medication administered via injection? |  |  |
| 8.7.1 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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| **9. Laboratory Technician Checklist** | **Yes** | **No** |
| 9.1 Does your project involve the use of equipment for testing purposes? |  |  |
| **If YES to 9.1:** |
| 9.2 Please list the equipment to be used in the testing protocol (NS 5.3): |
| Equipment / item | Equipment owner (organisation) |
| 1. |  |  |
| 2. |  |  |
| 3. |  |  |
| 4. |  |  |
| 5. |  |  |
| 6. |  |  |
| 7. |  |  |
| 9.3 Is this equipment used throughout the methodology considered new or innovative? |  |  |
| 9.4 Have the listed equipment items recently been calibrated? |  |  |
| 9.4.1 If **YES** what was the calibration date? | DD/MM/YYYY |
| 9.4.2 Briefly state the calibration method for each item: |
| 9.5 Have the listed equipment items been validated? |  |  |
| 9.5.1 If **NO,** will this equipment be validated prior to the research being conducted? |  |  |
| 9.5.1.1 If **YES,** state when validation will occur in the context of the project timeframes (Section 5) and explain how validation will be carried out: |
| 9.5.2 Can you provide equipment logbook information for maintenance and calibration if requested by the AIS Ethics Committee? |  |  |
| 9.6 Has all equipment with connection to mains power been safety tested and tagged? |  |  |

*\*For section 9.2, please add lines if necessary, or delete lines that are not used.*

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| **10. Participants****10.1 Description of Participants** |
| 10.1.1 Sport(s) |  |
| 10.1.2 Age Range |  |
| 10.1.3 Institutions involved |  |
| 10.1.4 Athletic Status(elite, sub-elite, novice, recreational, sedentary) |  |
| 10.1.5 Please provide a summary description of your participant population:*Recommended length: 1 – 2 short sentences* |
| 10.1.6 Projected number of participants |  |
| 10.1.6.1 Please explain the need for the specified number of participants (Power analysis): |
|  | **Yes** | **No** |
| 10.1.7 Are you seeking to collect sex and/or gender information from participants? |  |  |
| 10.1.7.1 If YES, please justify why this information is required*Please refer to the Australian Government Guidelines (Appendix 10a).* |
| 10.1.8 Criteria for participation |
| 10.1.8.1 Inclusion: |  |
| 10.1.8.2 Exclusion: |  |

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| **10.2 Specific Populations**  | **Yes** | **No** |
| 10.2.1 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) |  |  |
| 10.2.1.1 Does the project involve human foetuses or foetal tissue? |  |  |
| 10.2.2 If **YES** to any of the above, how are the specific ethical considerations being addressed? *Recommended length: 2 – 3 sentences per specific participant type.* |
| 10.2.3 Is translation of any research material for participants required? |  |  |
| 10.2.3.1 If **YES**, who is responsible for this translation?  |
| 10.2.4 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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| **10.3 Consent and Recruitment** | **Yes** | **No** |
| 10.3.1 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 2.2 and 2.3) |  |  |
| 10.3.1.1 If you are **not** seeking informed consent, explain why not:*Recommended length: 2 – 3 sentences* |
| Opt Out Consent (NS 2.3) |  |  |
| 10.3.1.2 Ifyou are seeking opt-out consent, explain why: *Recommended length: 2 – 3 sentences* |
| Consent Waiver (NS 2.3) |  |  |
| 10.3.1.3 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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| **10.4 Participant Recruitment** |  **Yes** | **No** |
| 10.4.1 Are you recruiting participants for active participation in this study? |  |  |
| 10.4.2 Are you recruiting participants in order to use their data in this study? |  |  |
| **If YES to 10.4.1 or 10.4.2:** |
| 10.4.3 Which of the following methods will you use to recruit participants: |
| E-mail  |  |  |
| Word of mouth  |  |  |
| Referral  |  |  |
| Direct correspondence with a team or coach  |  |  |
| 10.4.3.1 Other – please elaborate:*Recommended length: 1 – 2 short sentences* |
| 10.4.4 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.* |
| 10.4.5 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.* |
| 10.4.6 Is organisation approval required prior to recruitment? |  |  |
| 10.4.6.1 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.* |
| 10.4.7 Will participants receive any monetary or other benefits for their participation (NS 2.2.10)? |  |  |
| 10.4.7.1 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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| **10.5 Participant Follow-up and Support** | **Yes** | **No** |
| 10.5.1 Are there processes in place for participant follow up if any results yielded are abnormal or adverse?  |  |  |
| 10.5.1.1 Please explain your response to 10.5.1:*Recommended length: 2 – 3 sentences.* |
| 10.5.2 Will any feedback be provided to participants about the results of the research?  |  |  |
| 10.5.2.1 If **YES**, please explain how feedback will be provided:*Recommended length: 1 – 2 sentences.* |
| 10.5.3 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.*

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| **11. Data Management****11.1 Data Types** | **Yes** | **No** |
| 11.1.1 Please describe the data that will be collected:*Recommended length: list all data types to be used* |
| 11.1.2 Have you completed a survey of existing data to prevent duplication of research or results? |  |  |
| 11.1.2.1 If **YES**, please briefly explain your search methods and the locations searched.*Recommended length: 3 – 4 short sentences. Please list searched databases and locations.* |
| 11.1.3 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 |  |  |
| 11.1.3.1 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.* |

|  |  |  |
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| **11.2 Privacy and Security** | **Yes** | **No** |
| 11.2.1 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? |  |  |
| 11.2.2 Are you seeking approval to analyse retrospective data?  |  |  |
| 11.2.2.1 If **YES**, what is the data source?  |
| 11.2.2.2 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** |
| 11.2.3 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 |  |  |
| 11.2.3.1 Other identifiers – please list: |
| 11.2.3.2 If any of the categories in 11.2.3 apply, describe how you will maintain the anonymity of participants *(NS 3.1):**Recommended length: 3 – 4 sentences* |
| 11.2.3.3 If none of the categories in 11.2.3 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)* |  |  |
| 11.2.3.3.1 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** |
| 11.2.4 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.* |  |  |

|  |  |  |
| --- | --- | --- |
| **11.3 Data Access and Storage** | **Yes** | **No** |
| 11.3.1 Which organisation(s) will own the data collected in this project? |  |
| 11.3.2 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 |  |  |
| 11.3.2.1 Please explain which data will be accessed, by whom, and why:*Recommended length: 1 – 2 sentences per party.* |
| 11.3.3 Who will perform the data analysis? |
| 11.3.3.1 If the person / people performing data analysis is / are external to the research team, please provide their details: |
| Name | Organisation | Qualifications |
| 1. |  |  |
| 2. |  |  |
| 3. |  |  |
| 11.3.4 Where will each data type be stored? *Recommended length: 2 – 3 short sentences.*  |
| 11.3.5 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.* |
| 11.3.6 If you are not using Australian Sports Commission systems, what are your data storage backup measures?*Please list all measures.* |
| 11.3.7 How will you transmit data (if required) within the research team?*Recommended length: 1 – 2 short statements.* |
|  | **Yes** | **No** |
| 11.3.8 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.* |  |  |
| 11.3.8.1 If **YES**, please explain:*Recommended length: 3 – 4 sentences.* |
| 11.3.9 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.* |
| 11.3.10 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*. |  |  |
| 11.3.11 Do you require permission from a data custodian to access data?  |  |  |
| **If YES to 11.3.11:** |
| 11.3.11.1 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.* |
| 11.3.12 Please provide details of the authorised data custodian: |
| Name | Organisation | Contact Details (Phone or email) |
|  |  |  |

|  |  |  |
| --- | --- | --- |
| **12. Budget** | **Yes** | **No** |
| 12.1 Is the project funded? |  |  |
| 12.1.1 If **YES**, please attach written proof of funding approval to this submission. |
| 12.2 Budget required | $ |
| 12.3 Approved level of funding | $ |
| 12.4 Source(s) of funding |  |
| 12.5 Is there commercial interest in the project? |  |  |
| 12.5.1 If **YES**, has the commercial company involved been made aware of any publishing of results? *(NHMRC Code of Conduct 3.1.68)* |  |  |
| 12.6 Are there any ethical considerations related to funding this research? *e.g. Personal or other interest or investment in the outcomes of the study.* |  |  |
| 12.4.1 Please elaborate:*Recommended length: 2 – 3 sentences per consideration.* |

**Information to Participants**

**Research Title:**

**Principal Researcher:**

[your name] [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 2015 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 “check your substances” database at <https://checksubstances.asada.gov.au>”]

[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 1791, or by mail to The Secretary AIS Ethics Committee PO Box 176 Belconnen ACT 2616.

**‘INFORMED CONSENT’ FORM (Minor)**

Project Title:

Principal Researchers:

This is to certify that I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (*parent/guardian*) hereby agree to give permission to have my child participate as a volunteer in a scientific investigation as an authorised part of the research program of the Australian Sports Commission under the supervision of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (*supervisor*).

The investigation and my child’s 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 my child or myself may have had, and all such questions and enquiries have been answered to my satisfaction.
* I understand that my child is free to deny any answers to specific items or questions in interviews or questionnaires.
* I understand that my child is free to withdraw consent and to discontinue participation in the project or activity at any time, without disadvantage.
* I understand that my child is free to withdraw his/her data from analysis without disadvantage.
* I understand that any data or answers to questions will remain confidential with regard to my child’s identity.
* I certify to the best of my knowledge and belief, my child has no physical or mental illness or limitation that would increase their risk in participating in this investigation.
* My child is participating in this project of their own free will and my child has not been coerced in any way to participate.
* I have read and understand the product and policy information provided to me on behalf of my child 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] keeping my personal information.*

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

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 scientific investigation 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 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] keeping my personal information.*

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 scientific investigation 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 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**

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

Personal Information is defined as: ‘Information or an opinion about an identified individual, or an individual who is reasonably identifiable: whether the information or opinion is true or not and whether the information or opinion is recorded in a material form or not. (s 6, Privacy Act)

Personal information includes information such as:

* your name or address
* International rank and Sport
* photos

The object of this principal is to ensure that APP entities manage personal information in an open and transparent way. An APP entity must take such steps as are reasonable in the circumstances to implement practices, procedures and systems relating to the entity's functions or activities that will ensure that the entity complies with the Australian Privacy Principles and a registered APP code (if any) that binds the entity; and will enable the entity to deal with inquiries or complaints from individuals about the entity's compliance with the Australian Privacy Principles or such a code.

All personal information and data collected on Athletes through research is managed by the Australian Sports Commission and Institute of Sport under the ASC recordkeeping policy. Correspondence documenting scientific data must be kept for twenty five years before being destroyed, athlete medical information will be retained until the athlete reaches the age of seventy five.

**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 APP 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.

It is also noteworthy that Athletes who sign the Direct Athlete Servicing Agreement (DAS) do so with the understanding that the AIS may seek to retain any medical information obtained in respect of the athlete and the results of any tests or examinations carried out on the athlete may be used in research and publication in medical or scientific papers provided that such publication is done in such a way that the athletes identity remains anonymous.

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

If an APP entity is an agency or organisation, the entity must not collect personal information (other than sensitive information) unless the information is reasonably necessary for, or directly related to, one or more of the entity's functions or activities. An APP entity must not collect sensitive information about an individual unless the individual consents to the collection of the information and the information is reasonably necessary for, or directly related to, one or more of the entity's functions or activities. Information must be collected by lawful and fair means. An APP entity must collect personal information about an individual only from the individual unless: the individual consents to the collection of the information from someone other than the individual; or the entity is required or authorised by or under an Australian law, or a court/tribunal order, to collect the information from someone other than the individual; or it is unreasonable or impracticable to do so.

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

If an APP entity receives personal information and the entity did not solicit the information, the entity must, within a reasonable period after receiving the information, determine whether or not the entity could have collected the information under Australian Privacy Principal 3 if the entity had solicited the information. If the APP entity determines that the entity could not have collected the personal information and the information is not contained in a Commonwealth record, the entity must, as soon as practicable but only if it is lawful and reasonable to do so, destroy the information or ensure that the information is de-identified.

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

At or before the time an APP entity collects personal information about an individual, the entity must take such steps (if any) as are reasonable in the circumstances: to notify the individual or ensure the individual is aware of 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 the identity and contact details of the APP entity.

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

If an APP entity holds personal information about an individual that was collected for a particular purpose (the primary purpose), 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. It would be reasonable to expect the APP entity to use or disclose the sensitive information for the secondary purpose and the secondary purpose is directly related to the primary purpose; or if the information is not sensitive information — related to the primary purpose; or the use or disclosure of the information is required or authorised by or under an Australian law or a court/tribunal order. This applies in relation to the disclosure of personal information about an individual by an APP entity that is an agency if the agency is not an enforcement body, the information is biometric information or biometric templates, the recipient of the information is an enforcement body and the disclosure is conducted in accordance with the guidelines made by the Commissioner for the purposes of this paragraph. This principle does not apply to the use or disclosure by an organisation of personal information for the purpose of direct marketing or government related identifiers.

Under the DAS for the term of the agreement an Athlete authorises the AIS to retain any medical information obtained in respect of the athlete and the results of any tests or examinations carried out may be used in research and publication in medical or scientific papers provided that such publication is done in such a way that the athletes identity is not disclosed.

**Principle 7 — direct marketing**

If an organisation holds personal information about an individual, the organisation must not use or disclose the information for the purpose of direct marketing.

An organisation may use or disclose personal information (other than sensitive information) about an individual for the purpose of direct marketing if the organisation collected the information from the individual and it was expected that it would be used or disclosed for that purpose; and the organisation provides a simple means by which the individual may easily request not to receive direct marketing communications from the organisation. An organisation may use or disclose personal information (other than sensitive information) about an individual for the purpose of direct marketing if the organisation collected the information from the individual and the individual would not reasonably expect the organisation to use or disclose the information for that purpose or someone other than the individual; and either the individual has consented to the use or disclosure of the information for that purpose; or it is impracticable to obtain that consent. An organisation may use or disclose sensitive information about an individual for the purpose of direct marketing if the individual has consented to the use or disclosure of the information for that purpose. The organisation must provide a simple means by which the individual may easily request not to receive direct marketing communications from the organisation; and in each direct marketing communication with the individual the organisation includes a prominent statement that the individual may make such a request; or the organisation otherwise draws the individual's attention to the fact that the individual may make such a request; and the individual has not made such a request to the organisation.

This principle does not apply to the extent that any of the following apply:

* the Do Not Call Register Act 2006;
* the Spam Act 2003;
* any other Act of the Commonwealth, or a Norfolk Island enactment, prescribed by the regulations.

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

Before an APP entity discloses personal information about an individual to a person (the overseas recipient): who is not in Australia or an external Territory; the entity must take such steps as are reasonable in the circumstances to ensure that the overseas recipient does not breach the Australian Privacy Principles (other than Australian Privacy Principle 1) in relation to the information. This does not apply to the disclosure of personal information about an individual by an APP entity to the overseas recipient if the entity reasonably believes that: (i) the recipient of the information is subject to a law, or binding scheme, that has the effect of protecting the information in a way that, overall, is at least substantially similar to the way in which the Australian Privacy Principles protect the information; and (ii) there are mechanisms that the individual can access to take action to enforce that protection of the law or binding scheme or the disclosure of the information is required or authorised by or under an Australian law or a court/tribunal order.

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

An organisation must not adopt a government related identifier of an individual as its own identifier of the individual and must not use or disclose a government related identifier of an individual unless: the adoption of the government related identifier is required or authorised by or under an Australian law or a court/tribunal order; or the use or disclosure of the identifier is reasonably necessary for the organisation to verify the identity of the individual for the purposes of the organisation's activities or functions; or the use or disclosure of the identifier is reasonably necessary for the organisation to fulfil its obligations to an agency or a State or Territory authority; or the use or disclosure of the identifier is required or authorised by or under an Australian law or a court/tribunal order; or the organisation reasonably believes that the use or disclosure of the identifier is reasonably necessary for one or more enforcement related activities conducted by, or on behalf of, an enforcement body.

**Principle 10 — quality of personal information**

An APP entity must take such steps (if any) as are reasonable in the circumstances to ensure that the personal information that the entity collects is accurate, up-to-date and complete.

An APP entity must take such steps (if any) as are reasonable in the circumstances to ensure that the personal information that the entity 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**

If an APP entity holds personal information, the entity must take such steps as are reasonable in the circumstances to protect the information from misuse, interference, loss; and from unauthorised access, modification or disclosure.

If an APP entity holds personal information about an individual, no longer needs the information for any purpose and the information is not contained in a Commonwealth record or required under an Australian law (court/tribunal order) to retain the information, the entity must take such steps as are reasonable in the circumstances to destroy the information or to ensure that the information is de-identified.

**Principle 12 — access to personal information**

If an APP entity holds personal information about an individual, the entity must, on request by the individual, give the individual access to the information. If the APP entity is an agency; and the entity is required or authorised to refuse to give the individual access to the personal information by or under the Freedom of Information Act; or any other Act that provides for access by persons to documents; then, the entity is not required to give access to the extent that the entity is required or authorised to refuse to give access. The APP entity must respond to the request for access to the personal information within 30 days after the request is made; and give access to the information in the manner requested by the individual, if it is reasonable and practicable to do so. The entity must not charge the individual for the making of the request or for giving access to the personal information.

**Principle 13 — correction of personal information**

If an APP entity holds personal information about an individual; and either (i) the entity is satisfied that, having regard to a purpose for which the information is held, the information is inaccurate, out of date, incomplete, irrelevant or misleading; or (ii) the individual requests the entity to correct the information; the entity must take such steps (if any) as are reasonable in the circumstances to correct that information to ensure that, having regard to the purpose for which it is held, the information is accurate, up to date, complete, relevant and not misleading. If a request to correct information is made the APP entity must respond to the request within 30 days after the request is made and must not charge the individual for the making of the request, for correcting the personal information or for associating the statement with the personal information (as the case may be). If the APP entity refuses to correct the personal information as requested by the individual, the entity must give the individual a written notice that sets out the reasons for the refusal except to the extent that it would be unreasonable to do so; and the mechanisms available to complain about the refusal.

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 4.2*

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: \_\_\_/\_\_\_/\_\_\_

Organisation:

Position:

Qualifications:

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

Print name:

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

 Appendices

**1a** AISCOVID-19 Risk Assessment and Mitigation Plan for research:

<https://www.ais.gov.au/__data/assets/word_doc/0019/732340/AIS-COVID-19-RAMP-Research-Template.dotx>

**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

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