

Supplement Procedure for Students

Overview

The intentional use of prohibited substances and methods is becoming an increasingly prominent issue in the world of sport today. At the same time, cases of unintentional - or inadvertent - doping is on the rise as athletes are unaware of the risks involved in taking supplements. The Carnegie School of Sport are passionate about clean sport and protecting our students' health and their reputation by reducing the risk of them using a supplement that contains a prohibited substance. To reduce this risk, we have changed our practices, and supplements that we purchase for research projects will have gone through a risk minimisation certification service and wherever possible will be batch tested.

What does this mean?

If a supplement is registered as batch tested it means that, that specific batch of a product has been tested for prohibited substances and found to be free from those screened. Although there is still no guarantee that the supplement is 100% risk free, it does allow a greater confidence that the supplement provided is fit for consumption.

What are the implications?

Ultimately this process represents good practice and it will allow athletes to participate in research studies with batch tested products. As students preparing for dissertation projects there are a few things you need to be aware of when wanting to include supplements in your study.

Ethics Document

In your ethics document you must state what supplements you will be using and exactly how much per person is being consumed. You should make reference to whether the supplements are purchased batch-tested, from a 'Certified Manufacturer', or whether neither of these options are available. To be able to complete this section you will need to know where the learning support team will purchase the supplements. You can call into a dissertation drop-in session to discuss this. The safeguards put in place within the participant information sheet and consent form should also be highlighted within the Stage 2 form.

Your supplement calculations must also be signed off by your supervisor before testing can begin. This is to ensure that your calculations are accurate and safe for participants.

You must also state whether you are using batch tested supplements in your study or not in your information sheet. This is to ensure the participants know exactly what they

are consuming. You must therefore include one of the following statements in your information sheets that apply to your study.

NOTE: Since botanicals and herbs (i.e., CBD oil, maca root etc.) are either associated with increased risk of contamination/adulteration with banned substances or legal status is debatable, the School of Sport have taken the decision to not permit their use for any undergraduate or MSc projects. Use of colostrum is also not permitted. Colostrum is not prohibited by WADA, but it contains certain quantities of IGF-1 and other growth factors which are prohibited and can influence the outcome of anti-doping tests.

Information Sheet

Batch tested products - 'Consuming the supplements provided during this experiment does not pose any greater risk than purchasing and consuming these supplements in everyday life. Furthermore, the supplements provided during this experiment have been batch-tested to screen for prohibited substances. This significantly reduces the risk of any contamination but extremely small levels of impurities may still be present which are below the detection threshold of the test. Subsequently along with the manufacturers, we cannot provide a 100% guarantee that the supplement is completely free of prohibited substances. Please consider this information if you are a competitive athlete subject to drug testing'.

Non batch tested products but from a certified manufacturer - 'Consuming the supplements provided during this experiment does not pose any greater risk than purchasing and consuming these supplements in everyday life. Furthermore, the supplements provided during this experiment have been purchased from certified manufacturers who have passed appropriate quality control standards. This significantly reduces the risk of any contamination but we cannot guarantee that the supplement is free of prohibited substances. Please consider this information if you are a competitive athlete subject to drug testing'.

Non batch tested and not from a certified manufacturer - 'Consuming the supplements provided during this experiment does not pose any greater risk than purchasing and consuming these supplements in everyday life. However we cannot guarantee that the supplement is free of prohibited substances. Please consider this information if you are a competitive athlete subject to drug testing'.

All studies involving supplements

The participant information sheet must also state the ingredients contained within the supplements that are to be used during the experiment. It must be stated that participation is not allowed for anybody who has any known allergies to the ingredients or who has experienced any adverse reactions to the ingredients'.

Informed Consent

You must ensure that your participants have the appropriate information to give informed consent. Therefore, you must have one of the statements below in your consent form.

Batch tested products - I understand that the supplements provided during this experiment have been batch-tested but that some impurities may be present at levels below the detection threshold of the test. Subsequently it cannot be guaranteed that the supplement is completely free of prohibited substances.

Non batch tested products but from a certified manufacturer - I understand that the supplements provided during this experiment have been purchased from certified manufacturers but that this does not guarantee that the supplement is free of prohibited substances.

Non batch tested and not from a certified manufacturer - I understand that the researchers conducting this experiment cannot guarantee that the supplements provided are free of prohibited substances.

Risk Assessment

When including supplements in your project you must include a supplement risk assessment section in your full risk assessment document. This is to ensure that you understand the risks associated with supplement consumption. [Here is a link to a generic supplement risk assessment](#). You must make any necessary changes to this section of the risk assessment if there are any specific hazards associated with the supplement you are using. There is more information about writing a risk assessment for your dissertation [here](#).

Learning Officer Support

Come to a dissertation drop-in before submitting your ethics submission. Together we can work out if it is possible to buy batch tested items or from a certified supplier. This will then help you to complete all your ethics forms.

Questions to ask yourself when completing a dissertation ethics process:

1. Are you using supplements?
2. Have you spoken to the Learning Support team?
3. If you are using supplements, can they be purchased batch tested?
4. Have you stated this in your ethics, information sheets and consent forms?

5. Have you included a supplement risk assessment?
6. Has your supervisor signed off your calculations?

If you are unsure about any of these processes please come to the office FFG02a to talk about the options with a member of the Learning Support team during a dissertation drop-in session in person or online.

Level 6 Drop-in sessions - Monday 2-4pm

Level 7 Email the group email below for a meeting

If you cannot make on of these sessions please send an email to sports-science-learning-support@leedsbeckett.ac.uk

Appendix 1

Example caffeine calculations

My protein caffeine tablets

1 tablet = 200mg of caffeine

1 tablet weighs 600mg

Example 1:

You are testing an 80kg male with $3\text{mg}\cdot\text{kg}^{-1}$ of caffeine.

First you need to work out how much caffeine you need for that dose.

$$80 \times 3 = 240\text{mg (0.24g) of caffeine}$$

By looking at this information we can see that there is more caffeine required than we can obtain from one tablet. Therefore we will need to crush two tablets as each tablet has 200mg of caffeine.

We now need to work out the weight required to ensure the tablets have the correct amount of caffeine in them. Each tablet weighs 600mg (0.6g) and contains 200mg (0.2g) of caffeine. 200mg (0.2g) is one third of 600mg (0.6g). Therefore to work out how much of the tablet we want, we need to multiply the caffeine dose by 3.

$$240\text{mg} \times 3 = 720\text{mg (0.72g) total powder weight of tablet}$$

You then need to crush up 720mg (0.72g) of caffeine powder to put in the capsule. As each tablet weighs 600mg (0.6g) we know we are going to need just over one tablet to make one capsule. Therefore crush up two tablets and then weigh out the appropriate amount.

Example 2:

You are testing an 80kg male with $6\text{mg}\cdot\text{kg}^{-1}$ of caffeine.

$80 \times 6 = 480\text{mg}$ of caffeine required

$480 \times 3 = 1440\text{mg}$ total powder weight (1.44g)

HealthSpan Elite caffeine gum

1 piece = 100mg caffeine

Weight of 1 piece = 2g

Example 1:

You are testing an 80kg male with $3\text{mg}\cdot\text{kg}^{-1}$ of caffeine.

First you need to work out how much caffeine you need for that dose.

$80 \times 3 = 240\text{mg}$ (0.24g) of caffeine

By looking at this information we can see that there is more caffeine required than we can obtain from one piece. Therefore we will need to weigh out and measure how many pieces of gum we need.

We now need to work out the weight required to ensure the pieces have the correct amount of caffeine in them. Each piece weighs 2g (2000mg) and contains 100mg of caffeine. 2000mg divided by $100\text{mg} = 20$. Therefore we have to multiply the caffeine weight required by 20 to work out the weight of the gum required.

$240 \times 20 = 4800\text{mg}$ (4.8g)

You therefore need to weigh out 4.8g of caffeine gum.

Example 2

You are testing an 80kg male with $6\text{mg}\cdot\text{kg}^{-1}$ of caffeine.

$80 \times 6 = 480\text{mg}$ (0.48g) of caffeine required

$480 \times 20 = 9600\text{mg}$ (9.6g)



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CARNEGIE SCHOOL OF SPORT

Ethics Guidance Document

Effective Date: November 2019

Version: 1.2

**Prepared by: Dr Theocharis Ispoglou and
Professor Sue Backhouse**

Approved by:

**Guidelines for food and ergogenic supplement use within teaching and
research activities in the Carnegie School of Sport**

Note: this guide can be a reference point for both staff and students

Food Supplements	Legal Definition - Directive 2002/46/EC of the European Parliament and of the Council (DEP)
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Working definition of food supplements for the purpose of the guidelines:

Foodstuffs, the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients (e.g., vitamins and minerals) or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities (Legal Definition - Directive 2002/46/EC of the European Parliament and of the Council)

1) Purchasing of supplements

1a) Information

- Some supplements are available for purchase in a batch-tested form but this is not available for other supplements (see Table 1).
- The purchasing of batch-tested supplements reduces the risk of contamination and adulteration (and thus the risk of inadvertent doping test/negative health effects) but third party testing does not provide 100% guarantee that a product is safe for use.
- There are cost implications for purchasing batch-tested supplements. For example, the price of 2.5 kg of whey protein increases from £22.99 to £33.99. The cost differences for other supplements may be small (e.g., 1kg of creatine monohydrate increases from £11.99 to £12.99).
- Several certification systems for food supplements in sport have been established over the last 15 years. These certification systems all have in common:
 - systemic and batch-specific testing of products on behalf of the industry
 - providing manufacturers certificates of the tests performed
 - having a publicly accessible database of certified product batches
- At the time of the publication of this report, seven established certification systems were identified. In alphabetical order, these systems are:
 - BSCG Certified Drug Free
 - Cologne List
 - HASTA™ - Human and Supplement Testing Australia
 - Informed Choice
 - Informed Sport
 - NSF Certified for Sport
 - NZVT - Dutch Safeguards System for Dietary Supplements in Elite SportPurchasing supplements that have gone through third party testing via these companies reduces the risk of contamination and adulteration if batch tested options are not available.

1b) Recommendations

- Purchase supplements from companies listed as 'Certified Manufacturers' by third party testing organisations (e.g., Informed Sport) where available.
- Purchase batch tested products where available and report batch number. If non-batch tested supplements are deemed to be the preferred product over batch tested supplements, there has to be a strong and justifiable rationale. Cost of food supplements should not be a key driver for informing a team's decision which product to use.
- Add one of the following statements to the participant information sheets for any experiment involving supplements: a) if the supplements in this study are batch tested* -"Consuming the supplements provided during this experiment does not pose any greater risk than purchasing and consuming these supplements in everyday life. Furthermore, the supplements provided during this experiment have been batch-

tested to screen for banned substances. This significantly reduces the risk of any product contamination/adulteration. However, given the detection thresholds of doping control tests, we cannot provide a 100% guarantee that the supplement is completely absent of banned substances. Please consider this information if you are a competitive athlete subject to doping control". b) Non-batch tested products but from a certified manufacturer**-"Consuming the supplements provided during this experiment does not pose any greater risk than purchasing and consuming these supplements in everyday life. Furthermore, the supplements provided during this experiment have been purchased from certified manufacturers who have passed appropriate quality control standards. This significantly reduces the risk of any product contamination/adulteration, but we cannot guarantee that the supplement is free of banned substances. Please consider this information if you are a competitive athlete subject to drug testing". c) Non-batch tested and not from a certified manufacturer***-"Consuming the supplements provided during this experiment does not pose any greater risk than purchasing and

consuming these supplements in everyday life. However, we cannot guarantee that the supplement is free of banned substances. Please consider this information if you are a competitive athlete subject to drug testing".

- Add one of the following statements to the consent form for any experiment involving supplements: If supplements are used in this experiment, I understand that the supplement(s) involved are: *Batch-tested/**From a certified supplier/**Not from a certified supplier [please delete as appropriate]. There is information about supplements classification overleaf.
- In addition to the above, add also the following statement in the consent from: "If any type of supplements or food need to be consumed, I can confirm that I am not allergic to any of the ingredients listed on the label".
- The Stage 2 ethics form should make reference to whether the supplements are purchased from a 'Certified Manufacturer', batch-tested, or whether neither of these options were available. The safeguards put in place within the participant information sheet and consent form should also be highlighted within the Stage 2 form.

NOTE: Since botanicals and herbs (i.e., CBD oil, maca root etc.) are either associated with increased risk of contamination/adulteration with banned substances or legal status is debatable, the School of Sport have taken the decision to not permit their use for any undergraduate or MSc projects. Use of colostrum is also not permitted. Colostrum is not prohibited by WADA, but it contains certain quantities of IGF-1 and other growth factors which are prohibited and can influence the outcome of anti-doping tests. For any questions/queries please liaise with the Local Research Ethics Coordinators.

2)Preparation of supplements

2a) Information

- The risks associated with incorrectly preparing supplements has recently been highlighted by the accidental overdosing of caffeine in a sports science department at a UK university. Therefore, for each project involving the use of supplements students need to have the approved supplement calculation sheet signed by their supervisor before data collection commences.

2b) Recommendations

- All supplement dosage calculations are to be checked by the module or seminar leader for teaching activities, or by the primary supervisor for research activities and dissertations.
- Students must be supervised by an appropriately trained Learning Support Officer when preparing supplements.
- The risk assessment for supplement preparation must be included in ethics applications and followed for all activities involving supplement use (see Appendix 1).
- The safeguards highlighted in the above recommendations should be referred to within the Stage 2 ethics form.

3) Administration

3a) Information

- The dangers of excess caffeine consumption has recently been highlighted by the accidental overdosing of caffeine in a sports science department at a UK university.

3b) Recommendations

- The participant information sheet must state the ingredients contained within the supplements that are to be used during the experiment. It must be stated that participation is not allowed for anybody who has any known allergies to the ingredients or who has experienced any adverse reactions to the ingredients.
- Participants must not be provided with more than one dose of caffeine supplementation for consumption away from the laboratory (i.e., the participant must collect separate doses at the relevant time for any studies involving caffeine consumption on multiple occasions).
- The safeguards highlighted in the above recommendations should be referred to within the Stage 2 ethics form.

Table 1. Prices and availability of batch tested supplement products.

Supplement Name	Non Batch Tested			Batch Tested		
	Quantity	Supplier	Price	Quantity	Supplier	Price - Batch Tested
Impact Whey PRO	2.5kg	MyProtein	£22.99	2.5kg	MyProtein	£33.99
Creatine Monohydrate	1kg	MyProtein	£11.99	1kg	MyProtein	£12.99
Micellar Casein	1kg	MyProtein	£12.49	1kg	MyProtein	£13.99
L Glutamine	500g	MyProtein	£8.49	500g	MyProtein	£8.99
Beta Alanine	500g	MyProtein	£21.49	400g	Nutrition X	£24.99
BCAA (branch chain amino)	1kg	MyProtein	£33.49	1kg	MyProtein	£44.99
Beetroot Shots				Pack of 15x70ml	James White Drinks	£25.00
Beetroot Shots (Placebo)				x 1 75ml shot	James White Drinks	£10.00 each
Caffeine Gum				10 pieces (100mg caf per piece)	Elite Kick Start Gum	£24.95
Placebo Gum (Wrigleys gum)	64g	Sainsburys	#VALUE!			
Leucine	250g	MyProtein	£9.49	250g	Nutrition X	£17.99
Glucose	500g	Amazon	£2.75			
Maltodextrin	1kg	MyProtein		1kg	MyProtien	£4.49
Sodium Bicarbonate	500g	Dolphin Fitness	£2.95			
Lactose	500g	Blackburn Distributions	£13.00			
Dextrose	1kg	MyProtein	£3.99			
Sucralose	100g	MyProtein	£11.99			
L Arginine	500mg	Holland & Barratt	£4.49			

Note: Spreadsheet cells have been made black if the product is not available in either a batch tested or non batch tested form.

Appendix 1: Risk Assessment

Carnegie School of Sport

Risk Assessment. An Example

Procedure:	Preparation and administering of supplements
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Assessment Number:	3
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Date Assessed:	
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Assessed By:	Sports Science Learning Support Team
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Signed:	Position:
E. Payne	Lead Principal Learning Support Officer

Hazards:	Risks and Specific Control Measures:
Contamination	<p>There is a risk of contamination whilst laboratory users are preparing supplements.</p> <p><i>(L2xC1 = R2, Acceptable)</i></p> <p>Control Measures:</p> <ul style="list-style-type: none">Supplements to be prepared in the nutrition laboratory or in general use laboratories away for biohazard areas.

	<ul style="list-style-type: none"> ● Before and after preparation of supplements all surfaces should be cleaned using D10 Kitchen Detergent. ● Laboratory users should wash hands before and after supplement preparation. ● Laboratory users must wear PPE (gloves & lab coat). ● All hair should be tied back. ● Jewellery or nail varnish should not be worn during this process. ● All relevant equipment should be clearly labelled and stored in nutrition storage areas. <p>Residual Risk (L1xC1 = R1, Trivial)</p>
Excessive supplement ingestion	<p>There is a risk that quantities are made in excess and ingested that can cause side effects.</p> <p>(L2xC2 = R4, Moderate)</p> <p>Control Measures:</p> <ul style="list-style-type: none"> ● Supplements must be prepared following the agreed quantities with academic staff which should adhere to recommendations set within literature. ● Appropriately accurate scales should always be used to weigh supplements. ● Laboratory users should be supervised by a member of the learning support team whilst making up supplements. ● Participants must not be provided with more than one dose of caffeine supplementation for consumption away from the laboratory i.e. the participant must collect separate doses at the relevant time for any studies involving caffeine supplementation on multiple occasions.

	Residual Risk (L1xC2 = R2, Acceptable)
Allergies/Intolerances	<p>There is the potential that participants could have an allergy or intolerance to the supplement.</p> <p>(L1xC2 = R3, Acceptable)</p> <p>Control Measures:</p> <ul style="list-style-type: none"> The participant information sheet must state the ingredients contained within the supplements that are to be used during the experiment. It must be stated that participation is not allowed for anybody who has any known allergies to the ingredients or who has experienced any adverse reactions to the ingredients. <p>Residual Risk (L1xC2 = R2, Acceptable)</p>

Risk Evaluation (Overall):
<ul style="list-style-type: none"> Acceptable
General Control Measures:
<ul style="list-style-type: none"> Laboratory users to be trained in the correct use of scales and associated equipment to prepare supplements.

Emergency Procedures:
<ul style="list-style-type: none"> Sports Science teaching and research laboratories emergency procedure should be followed.

Monitoring Procedures:

- | |
|---|
| <ul style="list-style-type: none">• Laboratory users to be supervised whilst preparing supplements. |
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Review Period:	Annually
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Reviewed By:	Date:
Chair of Research Ethics Advisory Group	

LEARNING RESOURCE:

