

WORLD ANTI-DOPING CODE

INTERNATIONAL STANDARD

THERAPEUTIC USE EXEMPTIONS

2021

JANUARY 2019



International Standard for Therapeutic Use Exemptions

The World Anti-Doping Code International Standard for Therapeutic Use Exemptions (ISTUE) is a mandatory International Standard developed as part of the World Anti-Doping Program. It was developed in consultation with Signatories, public authorities and other relevant stakeholders.

The International Standard for Therapeutic Use Exemptions was first adopted in 2004 and came into effect on 1 January 2005. Further revisions were made in the was subsequently amended six times, the first-time effective January 2009, the second effective January 2010, the third effective January 2011, the fourth effective January 2015, and 2018. The enclosed ISTUE incorporates revisions the fifth effective January 2016, the sixth effective January 2019. A revised version was approved by the WADA Executive Committee on 20 September 2018. It will come into effect on at the World Conference on Doping in Sport in Katowice on 7 November 2019 and is effective as of 1 January 2019.

The official text of the International Standard for Therapeutic Use Exemptions shall be maintained by WADA and shall be published in English and French. In the event of any conflict between the English and French versions, the English version shall prevail 2021.

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PART ONE: INTRODUCTION, CODE PROVISIONS, INTERNATIONAL STANDARD PROVISIONS AND DEFINITIONS

1.0 Introduction and Scope

The *International Standard* for *Therapeutic Use Exemptions* is a mandatory *International Standard* developed as part of the World Anti-Doping Program.

The purpose of the *International Standard* for *Therapeutic Use Exemptions* is to establish (a) the conditions that must be satisfied in order for a *Therapeutic Use Exemption* (or *TUE*) to be granted, permitting the presence of a *Prohibited Substance* in an *Athlete's Sample* or the *Athlete's Use* or *Attempted Use*, *Possession* and/or *Administration* or *Attempted Administration* of a *Prohibited Substance* or *Prohibited Method* for therapeutic reasons; (b) the responsibilities imposed on *Anti- Doping Organizations* in making and communicating *TUE* decisions; (c) the process for an *Athlete* to apply for a *TUE*; (d) the process for an *Athlete* to get a *TUE* granted by one *Anti-Doping Organization* recognized by another *Anti-Doping Organization*; (e) the process for *WADA* to review *TUE* decisions; and (f) the strict confidentiality provisions that apply to the *TUE* process.

Terms used in this *International Standard* that are defined terms from the *Code* are written initalies italicized. Terms that are defined in this or another *International Standard* are underlined.

2.0 Code Provisions

The following articles in the <u>2015</u>2021 Code are directly relevant to the *International Standard* for *Therapeutic Use Exemptions*; they can be obtained by referring to the <u>Code</u> itself:

Code Article 4.4 Therapeutic Use Exemptions ("TUEs")-

4.4.1The presence of a *Prohibited Substance* or its *Metabolites* or *Markers*, and/or the *Use* or *Attempted Use*, *Possession* or *Administration* or *Attempted Administration* of a *Prohibited*

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- Substance or Prohibited Method shall not be considered an anti-doping rule violation if it is consistent with the provisions of a TUE granted in accordance with the International Standard for Therapeutic Use Exemptions.
- 4.4.2An Athlete who is not an International-Level Athlete should apply to his or her National Anti-Doping Organization for a TUE. If the National Anti-Doping Organization denies the application, the Athlete may appeal exclusively to the national level appeal body described in Articles 13.2.2 and 13.2.3.
- 4.4.3An Athlete who is an International-Level Athlete should apply to his or her International Federation.
 - 4.4.3.1Where the Athlete already has a TUE granted by his or her National Anti-Doping Organization for the substance or method in question, if that TUE meets the criteria set out in the International Standard for Therapeutic Use Exemptions, then the International Federation must recognize it. If the International Federation considers that the TUE does not meet those criteria and so refuses to recognize it, it must notify the Athlete and his or her National Anti-Doping Organization promptly, with reasons. The Athlete or the National Anti-Doping Organization shall have 21 days from such notification to refer the matter to WADA for review. If the matter is referred to WADA for review, the TUE granted by the National Anti-Doping

Organization remains valid for national-level Competition and Out-of-Competition Testing (but is not valid for international-level Competition) pending WADA's decision. If the matter is not referred to WADA for review, the TUE becomes invalid for any purpose when the 21-day review deadline expires.

4.4.3.2If the Athlete does not already have a TUE granted by his or her National Anti-Doping Organization for the substance or method in question, the Athlete must apply directly to his or her International Federation for a TUE as soon as the needarises. If the International Federation (or the National Anti-Doping Organization, where it has agreed to consider the application on behalf of the International Federation) denies the Athlete's application, it must notify the Athlete promptly, with reasons. If the International Federation grants the Athlete's application, itmust notify not only the Athlete but also his or her National Anti-Doping Organization, and if the National Anti-Doping Organization considers that the TUEdoes not meet the criteria set out in the International Standard for Therapeutic-Use Exemptions, it has 21 days from such notification to refer the matter to-WADA for review. If the National Anti-Doping Organization refers the matter to WADA for review, the TUE granted by the International Federation remains validfor international level Competition and Out-of-Competition Testing (but is not valid for national level Competition) pending WADA's decision. If the National Anti-Doping Organization does not refer the matter to WADA for review, the TUEgranted by the International Federation becomes valid for national-level Competition as well when the 21-day review deadline expires.

[Comment to Article 4.4.3: If the International Federation refuses to recognize a TUE granted by a National Anti-Doping Organization only because medical records or other information are missing that are needed to demonstrate satisfaction with the criteria in the International Standard for Therapeutic Use Exemptions, the matter should not be referred to WADA. Instead, the file should be completed and re-submitted to the International Federation.

If an International Federation chooses to test an Athlete who is not an



International-Level Athlete, it must recognize a TUE granted to that Athlete by his or her National Anti-Doping Organization.]

- 4.4.4A Major Event Organization may require Athletes to apply to it for a TUE if they wish to Use a Prohibited Substance or a Prohibited Method in connection with the Event. In that case:
 - 4.4.4.1The *Major Event Organization* must ensure a process is available for an *Athlete* to apply for a *TUE* if he or she does not already have one. If the *TUE* is granted, it is effective for its *Event* only.
 - 4.4.4.2Where the Athlete already has a TUE granted by his or her National Anti-Doping Organization or International Federation, if that TUE meets the criteria set out in the International Standard for Therapeutic Use Exemptions, the Major Event Organization must recognize it. If the Major Event Organization decides the TUE does not meet those criteria and so refuses to recognize it, it must notify the Athlete promptly, explaining its reasons.
 - 4.4.4.3A decision by a *Major Event Organization* not to recognize or not to grant a *TUE*—may be appealed by the *Athlete* exclusively to an independent body established or appointed by the *Major Event Organization* for that purpose. If the *Athlete* does not appeal (or the appeal is unsuccessful), he or she may not *Use* the substance or

method in question in connection with the *Event*, but any *TUE* granted by his orher *National Anti-Doping Organization* or International Federation for that substance or method remains valid outside of that *Event*.

[Comment to Article 4.4.4.3: For example, the CAS Ad Hoc Division or a similar body may act as the independent appeal body for particular Events, or WADA may agree to perform that function. If neither CAS nor WADA are performing that function, WADA retains the right (but not the obligation) to review the TUE decisions made in connection with the Event at any time, in accordance with Article 4.4.6.]

- 4.4.5If an Anti-Doping Organization chooses to collect a Sample from a Person who is not an International-Level or National-Level Athlete, and that Person is Using a Prohibited Substance or Prohibited Method for therapeutic reasons, the Anti-Doping Organization may permit him or her to apply for a retroactive TUE.
- 4.4.6WADA must review an International Federation's decision not to recognize a TUE granted by the National Anti-Doping Organization that is referred to it by the Athlete or the Athlete's National Anti-Doping Organization. In addition, WADA must review an International Federation's decision to grant a TUE that is referred to it by the Athlete's National Anti-Doping Organization. WADA may review any other TUE decisions at any time, whether upon request by those affected or on its own initiative. If the TUE decision being reviewed meets the criteria set out in the International Standard for Therapeutic Use Exemptions, WADA will not interfere with it. If the TUE decision does not meet those criteria, WADA will-reverse it.

[Comment to Article 4.4.6: WADA shall be entitled to charge a fee to cover the costs of (a) any review it is required to conduct in accordance with Article 4.4.6; and (b) any review it chooses to conduct, where the decision being reviewed is reversed.]

4.4.7Any TUE decision by an International Federation (or by a National Anti-Doping Organization where it has agreed to consider the application on behalf of an International Federation) that is not reviewed by WADA, or that is reviewed by WADA but is not reversed upon



review, may be appealed by the Athlete and/or the Athlete's National Anti-Doping-Organization, exclusively to CAS.

[Comment to Article 4.4.7: In such cases, the decision being appealed is the International Federation's TUE decision, not WADA's decision not to review the TUE decision or (having reviewed it) not to reverse the TUE decision. However, the time to appeal the TUE decision does not begin to run until the date that WADA communicates its decision. In any event, whether the decision has been reviewed by WADA or not, WADA shall be given notice of the appeal so that it may participate if it sees fit.]

- 4.4.8A decision by WADA to reverse a TUE decision may be appealed by the Athlete, the National Anti-Doping Organization and/or the International Federation affected, exclusively to CAS.
- 4.4.9A failure to take action within a reasonable time on a properly submitted application for grant/recognition of a *TUE* or for review of a *TUE* decision shall be considered a denial of the application.
- Code Article 13.4 Appeals relating Relating to TUEs
 TUE decisions may be appealed exclusively as provided in Article 4.4.

3.0 Definitions and Interpretation

3.1 Defined terms from the 20152021 Code that are used in the *International Standard* for *Therapeutic Use Exemptions*:

ADAMS: The Anti-Doping Administration and Management System is a Web-based database management tool for data entry, storage, sharing, and reporting designed to assist stakeholders and *WADA* in their anti-doping operations in conjunction with data protection legislation.

Administration: Providing, supplying, supervising, facilitating, or otherwise participating in the Use or Attempted Use by another Person of a Prohibited Substance or Prohibited Method. However, this definition shall not include the actions of bona fide medical personnel involving a Prohibited Substance or Prohibited Method used Used for genuine and legal therapeutic purposes or other acceptable justification and shall not include actions involving Prohibited Substances which are not prohibited in Out-of-Competition Testing unless the circumstances as a whole demonstrate that such Prohibited Substances are not intended for genuine and legal therapeutic purposes or are intended to enhance sport performance.

Adverse Analytical Finding: A report from a WADA-accredited laboratory or other WADA- approved laboratory that, consistent with the *International Standard* for Laboratories—and related Technical Documents, identifies, establishes in a Sample the presence of a *Prohibited Substance* or its *Metabolites* or *Markers*—(including elevated quantities of endogenous substances) or evidence of the Use of a *Prohibited Method*.

Anti-Doping Organization: A<u>WADA</u> or a Signatory that is responsible for adopting rules for initiating, implementing or enforcing any part of the *Doping Control* process. This includes, for example, the International Olympic Committee, the International Paralympic Committee, other *Major Event Organizations* that conduct *Testing* at their *Events*, <u>WADA</u>, International Federations, and *National Anti-Doping Organizations*.

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Athlete: Any Person who competes in sport at the international level (as defined by each International Federation) or the national level (as defined by each National Anti-Doping Organization). An Anti-Doping Organization has discretion to apply anti-doping rules to an Athlete who is neither an International-Level Athlete nor a National-Level Athlete, and thus to bring them within the definition of "Athlete"." In relation to Athletes who are neither International-Level nor National-Level Athletes, an Anti-Doping Organization may elect to: conduct limited Testing or no Testing at all; analyze Samples for less than the full menu of Prohibited Substances; require limited or no whereabouts information; or not require advance TUEs. However, if an Article 2.1, 2.3 or 2.5 anti-doping rule violation is committed by any Athlete over whom an Anti-Doping Organization has elected to exercise its authority to test and who competes below the international or national level, then the Consequences set forth in the Code (except Article 14.3.2) must be applied. For purposes of Article 2.8 and Article 2.9 and for purposes of anti- doping information and education Education, any Person who participates in sport under the authority of any Signatory, government, or other sports organization accepting the Code is an Athlete.

[Comment: This definition makes it clear that all to Athlete: Individuals who participate in sport may fall in one of five categories:

1) International-Level Athlete, 2) National-Level Athlete, 3) individuals who are not International or National-Level Athletes but over whom the International Federation or National Anti-Doping Organization has chosen to exercise authority, 4) Recreational Athlete, and 5) individuals over whom no International Federation or National Anti-Doping Organization has, or has chosen to, exercise authority. All International and National-Level Athletes are subject to the anti-doping rules of the Code, with the precise definitions of international- and national- level sport to be set forth in the anti-doping rules of the International Federations and National Anti-Doping Organizations, respectively. The definition also allows each National Anti-Doping Organization, if it chooses to do so, toexpand its anti-doping program beyond International- or National-Level Athletes to competitors at lower levels of Competition or to individuals who engage in fitness activities but do not compete at all. Thus, a National Anti- Doping Organization could, for example, elect to test recreational-level competitors but not require advance TUEs. But an anti-doping rule violation involving an Adverse Analytical Finding or Tampering, results in all of the Consequences provided for in the Code (with the exception of Article 14.3.2). The decision on whether Consequences apply to recreational-level Athletes who engage infitness activities but never compete is left to the National Anti- Doping Organization. In the same manner, a Major Event Organization holding an Event only for masters-level competitors could elect to test the competitors but not analyze Samples for the full menu of Prohibited Substances. Competitors at all levels of Competition should receive the benefit of anti-doping information and education.] National Anti-Doping Organizations.]

Attempt: Purposely engaging in conduct that constitutes a substantial step in a course of conduct planned to culminate in the commission of an anti-doping rule violation. Provided, however, there shall be no anti-doping rule violation based solely on an **Attempt** to commit a violation if the **Person** renounces the **Attempt** prior to it being discovered by a third party not involved in the **Attempt**.

CAS: The Court of Arbitration for Sport.

Code: The World Anti-Doping Code.

Competition: A single race, match, game or singular sport contest. For example, a basketball game or the finals of the Olympic 100-meter race in athletics. For stage races

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other sport contests where prizes are awarded on a daily or other interim basis the distinction between a *Competition* and an *Event* will be as provided in the rules of the applicable International Federation.

Event: A series of individual *Competitions* conducted together under one ruling body (e.g., the Olympic Games, FINA World Championships of an International Federation, or Pan American Games).

In-Competition: Unless provided otherwise in the rules of an International Federation or the ruling body of the *Event* in question, "In-Competition" means the The period commencing twelve hoursat 11:59 p.m. on the day before a Competition in which the Athlete is scheduled to participate through the end of such Competition and the Sample collection process related to such Competition. Provided, however, WADA may approve, for a particular sport, an alternative definition if an International Federation provides a compelling justification that a different definition is necessary for its sport; upon such approval by WADA, the alternative definition shall be followed by all Major Event Organizations for that particular sport.

[Comment to In-Competition: Having a universally accepted definition for In-Competition provides greater harmonization among Athletes across all sports, eliminates or reduces confusion among Athletes about the relevant timeframe for In-Competition Testing, avoids inadvertent Adverse Analytical Findings in between Competitions during an Event and assists in preventing any potential performance enhancement benefits from substances prohibited Out-of-Competition being carried over to the Competition period.]

International Event: An Event or Competition where the International Olympic Committee, the International Paralympic Committee, an International Federation—or, a Major Event Organization, or another international sport organization is the ruling body for an Event may establish an "In Competition" period that is different than the Event Period the Event or appoints the technical officials for the Event.]

International-Level Athlete: Athletes who compete in sport at the international level, as defined by each International Federation, consistent with the International Standard for Testing and Investigations.

[Comment to International-Level Athlete: Consistent with the International Standard for Testing and Investigations, the International Federation is free to determine the criteria it will use to classify Athletes as International-Level Athletes, e.g., by ranking, by participation in particular International Events, by type of license, etc. However, it must publish those criteria in clear and concise form, so that Athletes are able to ascertain quickly and easily when they will become classified as International-Level Athletes. For example, if the criteria include participation in certain International Events, then the International Federation must publish a list of those International Events.]

International Standard: A standard adopted by WADA in support of the Code. Compliance with an International Standard (as opposed to another alternative standard, practice or procedure) shall be sufficient to conclude that the procedures addressed by the International Standard were performed properly. International Standards shall include any Technical Documents issued pursuant to the International Standard.



Major Event Organizations: The continental associations of *National Olympic Committees* and other international multi-sport organizations that function as the ruling body for any continental, regional or other *International Event*.

National Anti-Doping Organization: The entity(ies) designated by each country as possessing the primary authority and responsibility to adopt and implement anti-doping rules, direct the collection of *Samples*, the management of manage test results, and the conduct of hearings Results Management at the national level. If this designation has not been made by the competent public authority(ies), the entity shall be the country's National Olympic Committee or its designee.

National-Level Athlete: Athletes who compete in sport at the national level, as defined by each *National Anti-Doping Organization*, consistent with the *International Standard* for *Testing* and Investigations.

Out-of-Competition: Any period which is not In-Competition.

Possession: The actual, physical *Possession*, or the constructive *Possession* (which shall be found only if the *Person* has exclusive control or intends to exercise control over the *Prohibited Substance* or *Prohibited Method* or the premises in which a *Prohibited Substance* or *Prohibited Method* exists); provided, however, that if the *Person* does not have exclusive control over the *Prohibited Substance* or *Prohibited Method* or the premises in which a *Prohibited Substance* or *Prohibited Method* exists, constructive *Possession* shall only be found if the *Person* knew about the presence of the *Prohibited Substance* or *Prohibited Method* and intended to exercise control over it. Provided, however, there shall be no anti- doping rule violation based solely on *Possession* if, prior to receiving notification of any kind that the *Person* has committed an anti-doping rule violation, the *Person* has taken concrete action demonstrating that the *Person* never intended to have *Possession* and has renounced *Possession* by explicitly declaring it to an *Anti-Doping Organization*. Notwithstanding anything to the contrary in this definition, the purchase (including by any electronic or other means) of a *Prohibited Substance* or *Prohibited Method* constitutes *Possession* by the *Person* who makes the purchase.

[Comment to Possession: Under this definition, anabolic steroids found in an Athlete's car would constitute a violation unless the Athlete establishes that someone else used the car; in that event, the Anti-Doping Organization must establish that, even though the Athlete did not have exclusive control over the car, the Athlete knew about the anabolic steroids and intended to have control over the steroidsthem. Similarly, in the example of anabolic steroids found in a home medicine cabinet under the joint control of an Athlete and spouse, the Anti-Doping Organization must establish that the Athlete knew the steroids were in the cabinet and that the Athlete intended to exercise control over the steroidsthem. The act of purchasing a Prohibited Substance alone constitutes Possession, even where, for example, the product does not arrive, is received by someone else, or is sent to a third party address.]

Prohibited List: The List identifying the Prohibited Substances and Prohibited Methods.

Prohibited Method: Any method so described on the *Prohibited List*.

Prohibited Substance: Any substance, or class of substances, so described on the *Prohibited List*.

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Signatories: Those entities signing the Code and agreeing to comply with the Code, as provided in Article 23. Recreational Athlete: A natural Person who is so defined by the relevant National Anti- Doping Organization; provided, however, the term shall not include any Person who, within the five (5) years prior to committing any anti-doping rule violation, has been an International- Level Athlete (as defined by each International Federation consistent with the International Standard for Testing and Investigations) or National-Level Athlete (as defined by each National Anti-Doping Organization consistent with the International Standard for Testing and Investigations), has represented any country in an International Event in an open category or has been included within any Registered Testing Pool or other whereabouts information pool maintained by any International Federation or National Anti-Doping Organization.

[Comment to Recreational Athlete: The term "open category" is meant to exclude competition that is limited to junior or age group categories.]

Results Management: The process encompassing the timeframe between notification as per Article 5 of the *International Standard* for *Results Management*, or in certain cases (e.g., *Atypical Finding*, *Athlete Biological Passport*, *Whereabouts Failure*), such pre-notification steps expressly provided for in Article 5 of the *International Standard* for *Results Management*, through the charge until the final resolution of the matter, including the end of the hearing process at first instance or on appeal (if an appeal was lodged).

Sample or Specimen: Any biological material collected for the purposes of *Doping Control*.

[Comment to Sample or Specimen: It has sometimes been claimed that the collection of blood Samples violates the tenets of certain religious or cultural groups. It has been determined that there is no basis for any such claim.]

Testing: The parts of the *Doping Control* process involving test distribution planning, *Sample* collection, *Sample* handling, and *Sample* transport to the laboratory.

<u>Therapeutic Use Exemption (TUE):</u> A Therapeutic Use Exemption, as described allows an Athlete with a medical condition to use a Prohibited Substance or Prohibited Method, but only if the conditions set out in Article 4.4 and the International Standard for Therapeutic Use Exemptions are met.

Use: The utilization, application, ingestion, injection or consumption by any means whatsoever of any *Prohibited Substance* or *Prohibited Method*.

WADA: The World Anti-Doping Agency.

3.2 Further defined term Defined terms from the International Standard for the Protection of Privacy and Personal Information that is used in the International Standard for Therapeutic Use Exemptions:

Personal Information: Information, including without limitation <u>Sensitive Personal Information</u>, relating to an identified or identifiable *Participant* or <u>relating to</u> other <u>Persons Person</u> whose information is <u>Processed</u> solely in the context of an <u>Anti-Doping Organization's Anti-Doping Organization's Anti-Doping Activities.</u>

[3.2 Comment to Personal Information: It is understood that Personal Information includes,

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but is not limited to, information relating to an Athlete's name, date of birth, contact details and

sporting affiliations, whereabouts, designated therapeutic use exemptions TUEs (if any), anti-doping test results, and results management Management (including disciplinary hearings, appeals and sanctions). Personal Information also includes personal details and contact information relating to other Persons, such as medical professionals and other Persons working with, treating or assisting an Athlete in the context of Anti-Doping Activities. Such information remains Personal Information and is regulated by this International Standard for the entire duration of its Processing, irrespective of whether the relevant individual remains involved in organized sport.]

<u>Processing</u> (and its cognates, <u>Process</u> and <u>Processed</u>): Collecting, accessing, retaining, storing, disclosing, transferring, transmitting, amending, deleting or otherwise making use of Personal Information.

3.3 Further defined Defined terms specific to the International Standard for Therapeutic Use Exemptions:

Therapeutic: Of or relating to the treatment of a medical condition by remedial agents or methods; or providing or assisting in a cure.

Therapeutic Use Exemption Committee (or "TUEC"): The panel established by an *Anti-Doping Organization* to consider applications for *TUEs*.

WADA TUEC: The panel established by WADA to review the TUE decisions of other Anti-Doping Organizations.

3.4 Interpretation:

- 3.4.1 The official text of the *International Standard* for *Therapeutic Use Exemptions* shall be published in English and French. In the event of any conflict between the English and French versions, the English version shall prevail.
- 3.4.1 Unless otherwise specified, references to articles are references to articles of Like the Code, the International Standard for Therapeutic Use Exemptions. has been drafted giving consideration to the principles of proportionality, human rights, and other applicable legal principles. It shall be interpreted and applied in that light.
- 3.4.2 The comments annotating various provisions of the *International Standard* for *Therapeutic Use Exemptions* shall be used to interpret that <u>guide its</u> interpretation.
 - 3.4.4 <u>Unless otherwise specified, references to Sections and Articles are references to Sections and Articles of the International Standard for Therapeutic Use Exemptions.</u>
 - 3.4.5 Where the term "days" is used in the *International Standard* for *Therapeutic Use Exemptions*, it shall mean calendar days unless otherwise specified.

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3.4.6 The Annexes to the *International Standard* for *Therapeutic Use Exemptions* have the same mandatory status as the rest of the *International Standard*.

3.4.3The official text of the International Standard for Therapeutic Use Exemptions shall be maintained by WADA and shall be published in English and French. In the event of any conflict between the English and French versions, the English version shall prevail.

PART TWO: STANDARDS AND PROCESS FOR GRANTING TUES

4.0 Obtaining a TUE

4.1 An Athlete who needs to Use a Prohibited Substance or Prohibited Method for Therapeutic reasons must apply for and obtain a TUE under Article 4.2 prior to Using or Possessing the substance or method in question.

However, an *Athlete* may apply retroactively for a *TUE* (but must still meet the conditions in Article 4.2) if one of any of the following exceptions applies:

- a) Emergency or urgent treatment of a medical condition was necessary;
- <u>b)</u> There was insufficient time, opportunity or other exceptional circumstances that prevented the *Athlete* from submitting (or the TUEC to consider) an application for the *TUE* prior to *Sample* collection;
- c) <u>Due to national level prioritization of certain sports, the *Athlete's National Anti-Doping Organization* did not permit or require the *Athlete* to apply for a prospective *TUE* (see comment to Article 5.1);</u>
- d) If an Anti-Doping Organization chooses to collect a Sample from an Athlete who is not an International-Level Athlete or National-Level Athlete, and that Athlete is Using a Prohibited Substance or Prohibited Method for Therapeutic reasons, the Anti-Doping Organization must permit the Athlete to apply for a retroactive TUE; or
 - <u>e)</u> <u>The Athlete Used Out-of-Competition</u>, for Therapeutic reasons, a <u>Prohibited Substance</u> that is only prohibited <u>In-Competition</u>.

[Comment to Article 4.1(c), (d) and (e): Such Athletes are strongly advised to have a medical file prepared and ready to demonstrate their satisfaction of the TUE conditions set out at Article 4.2, in case an application for a retroactive TUE is necessary following Sample collection.]

[Comment to Article 4.1(e): This seeks to address situations where, for Therapeutic reasons, an Athlete Uses a substance Out-of-Competition that is only prohibited In-Competition, but there is a risk that the substance will remain in their system In-Competition. In such situations, the Anti-Doping Organization must permit the Athlete to apply for a retroactive TUE (where the Athlete has not applied in advance). This also seeks to prevent Anti-Doping Organizations from having to assess advance TUE applications that may not be necessary.]

4.1 An Athlete may be granted a TUE if (and only if) he/she can show, by aon the balance of probability probabilities, that each of the following conditions is met:

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a. The *Prohibited Substance* or *Prohibited Method* in question is needed to treat an acute or chronica diagnosed medical condition, such that the *Athlete* would experience a significant impairment to health if supported by relevant clinical evidence.

[Comment to Article 4.2(a): The Use of the Prohibited Substance or Prohibited Method were to may be withheld part of a necessary diagnostic investigation rather than a treatment per se.]

b. The <u>Therapeutic</u> Use of the <u>Prohibited Substance</u> or <u>Prohibited Method</u> is <u>highly unlikely to will not</u>, on the <u>balance of probabilities</u>, produce any additional enhancement of performance beyond what might be anticipated by a return to the <u>Athlete</u>'s normal state of health following the treatment of the <u>acute or chronic</u> medical condition.

c.There is no reasonable <u>Therapeutic</u> alternative to the <u>Use</u> of the <u>[Comment to Article 4.2(b): An Athlete's normal state of health will need to be determined on an individual basis. A normal state of health for a specific Athlete is their state of health but for the medical condition for which the Athlete is seeking a TUE.]</u>

<u>c)</u> The Prohibited Substance or Prohibited Method is an indicated treatment for the medical condition, and there is no reasonable permitted Therapeutic alternative.

[Comment to Article 4.2(c): The physician must explain why the treatment chosen was the most appropriate, e.g. based on experience, side-effect profiles or other medical justifications, including, where applicable, geographically specific medical practice, and the ability to access the medication. Further, it is not always necessary to try and fail alternatives before using the Prohibited Substance or Prohibited Method.]

d. The necessity for the *Use* of the *Prohibited Substance* or *Prohibited Method* is not a consequence, wholly or in part, of the prior *Use* (without a *TUE*) of a substance or method which was prohibited at the time of such *Use*.

[Comment to 4.1: Article 4.2: The WADA documents titled "TUE Physician Guidelines", posted on WADA's website, should be used to assist in the application of these criteria in relation to particular medical conditions.

The granting of a TUE is based solely on consideration of the conditions set out in Article 4.2. It does not consider whether the Prohibited Substance or Prohibited Method is the most clinically appropriate or safe, or whether its Use is legal in all jurisdictions.

When <u>aan International Federation or Major Event Organization TUEC</u> is deciding whether or not to recognize a TUE granted by another Anti-Doping Organization (see Article 7, below), and when WADA is reviewing a decision to grant (or not to grant) a TUE (see Article 8, below), the issue will be the same as it is for a <u>TUEC</u> that is considering an application for a TUE under <u>article Article</u> 6, <u>below</u>, i.e., has the Athlete demonstrated <u>by aon the</u> balance of <u>probability probabilities</u> that each of the conditions set out in <u>article 4.1 Article 4.2</u> is met?

The WADA documents titled "Medical Information to Support the Decisions of <u>TUECs</u>", posted on WADA's website, should be used to assist in the application of these criteria in relation to particular medical conditions.]

4.3 4.2Unless one of the exceptions set out in Article 4.3 applies, an Athlete who needs to Use-

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a Prohibited Substance or Prohibited Method for Therapeutic reasons must obtain a TUE prior to Using or Possessing the substance or method in question.

4.3AnIn exceptional circumstances and notwithstanding any other provision in this *International Standard*for *Therapeutic Use Exemptions*, an *Athlete* may enlyapply for and be granted retroactive approval for his/hertheir Therapeutic Use of a *Prohibited Substance* or *Prohibited Method* (i.e.,if, considering the purpose of the *Code*, it would be manifestly unfair not to grant a retroactive *TUE*) if:

a.Emergency treatment or treatment of an acute medical condition was necessary; or
b.Due to other exceptional circumstances, there was insufficient time or opportunity for the Athlete to submit, or for the TUEC to consider, an For International-Level Athletes and National-Level Athletes, an Anti-Doping Organization may grant an Athlete's application for the TUE prior to Sample collection; or

c.The applicable rules required the Athlete (see comment to Article 5.1) or permitted the Athlete (see Code Article 4.4.5) to apply for a retroactive TUE; or [Comment to 4.3(c): Such Athletes are strongly advised to have a medical file prepared and ready to demonstrate their satisfaction of the TUE conditions set out at Article 4.1, in case an application for a retroactive TUE is necessary following Sample collection.]
d.It is agreed, by WADA and by the pursuant to this Article only with the prior approval of WADA (and WADA may in its absolute discretion agree with or reject the Anti-Doping Organization's decision).

For Athletes who are not International-Level Athletes or National-Level Athletes, the relevant Anti-Doping Organization to whom themay grant an Athlete's application for a retroactive TUE is or would be made, that fairness requires the pursuant to this Article without first consulting WADA; however, WADA may at any time review an Anti-

<u>Doping Organization's decision to grant ef</u> a retroactive <u>TUE pursuant to this Article, and may in its absolute discretion, agree with or reverse the decision.</u>

<u>fComment to 4.3(d): IfAny decision made by</u> WADA and/or <u>thean</u> Anti-Doping Organization do not agree to the application of under this Article 4.3(d), that may not be challenged either as a defense to proceedings for an anti-doping rule violation, or by way of appeal, or otherwise.

All decisions of an Anti-Doping Organization under this Article 4.3, whether granting or denying a TUE, must be reported through ADAMS in accordance with Article 5.5.

[Comment to Article 4.3: For the avoidance of doubt, retroactive approval may be granted under Article 4.3 even if the conditions in Article 4.2 are not met (although satisfaction of such conditions will be a relevant consideration). Other relevant factors might include the reasons why the Athlete did not apply in advance; the Athlete's experience; whether the Athlete declared the Use of the substance or method on the Doping Control form; and the recent expiration of the Athlete's TUE. In making its decision, WADA may, at its discretion, consult with a member(s) of a WADA TUEC.]

5.0 TUE Responsibilities of Anti-Doping Organizations

5.1 Code Article 4.4 specifies (a) which Anti-Doping Organizations have authority to make TUE decisions; (b) how those TUE decisions should be recognized and respected by other Anti-Doping Organizations; and (c) when TUE decisions may be reviewed and/or appealed.

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[Comment to <u>Article 5.1</u>: See Annex 1 for a flow-chart Code Article 4.4 Flowchart summarizing the key provisions of Code Article 4.4.

Code Article 4.4.2 specifies the authority of a National Anti-Doping Organization to make TUE decisions in respect of Athletes who are not International-Level Athletes. In case of dispute as to which National Anti-Doping Organization should deal with the TUE application of an Athlete who is not an International-Level Athlete, WADA will decide. WADA's decision will be final and not subject to appeal.

Where national policy requirements and imperatives lead a National Anti-Doping Organization to prioritize certain sports over others in its test distribution planning (as contemplated by Article 4.4.1 of the International Standard for Testing and Investigations), the National Anti-Doping Organization may decline to consider advance applications for TUEs from Athletes in some or all of the non-priority sports, but in that case it must permit any such Athlete from whom a Sample is subsequently collected to apply for a retroactive TUE. The National Anti-Doping Organization should publicize any such policy on its website for the benefit of affected Athletes.

Code Article 4.4.2 specifies the authority of a National Anti-Doping Organization to make TUE decisions in respect of Athletes who are not International-Level Athletes. In case of dispute as to which National Anti-Doping Organization should deal with the TUE application of an Athlete who is not an International-Level Athlete, WADA will decide. WADA's decision will be final and not subject to appeal.]

- For the avoidance of doubt, when a National Anti-Doping Organization grants a TUE to an Athlete, that TUE is valid at national level on a global basis and does not need to be formally recognized by other National Anti-Doping Organizations under Article 7.0 (for example, if an Athlete is granted a TUE by their National Anti-Doping Organization and then trains or competes in the country of another National Anti-Doping Organization, that TUE will be valid if the Athlete is then tested by such other National Anti-Doping Organization).
- **5.2**Each National Anti-Doping Organization, International Federation and Major Event Organization must establish a <u>TUEC</u> to consider whether applications for grant or recognition of *TUEs* meet the conditions set out in Article 4.14.2.

[Comment to 5.2: Article 5.3: For the avoidance of doubt, the fulfilment of the conditions set out in Articles 4.1 and 4.3 may be determined by the relevant Anti-Doping Organization in consultation with a member(s) of the TUEC.

While a Major Event Organization may choose to recognize pre-existing TUEs automatically, there must be a mechanism for Athletes participating in the Event to obtain a new TUE if the need arises. It is up to each Major Event Organization whether it sets up its own <u>TUEC</u> for this purpose, or rather whether it outsources the task by agreement to a third party (such as Sport Accord). The aim in each case should be to ensure that Athletes competing in such Events have the ability to obtain TUEs quickly and efficiently before they compete.]

<u>a. TUECs</u> should include at least three <u>(3)</u> physicians with experience in the care and treatment of *Athletes* and a sound knowledge of clinical, sports and exercise medicine. In cases involving where specific expertise is required (for example, for *Athletes* with

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impairments, at least one <u>TUEC</u> member should possess general experience in the care and treatment of *Athletes* with impairments, or possess specific experience in relation where the substance or method pertains to the *Athlete's* particular impairment(s).

- b.In order to ensure a level of independence of decisions, at least a majority of the members of aone (1) TUEC member or expert should have no political responsibility in the Anti-Doping Organization that appoints them. All possess such expertise. One (1) physician member should act as chair of the TUEC.
- b) In order to ensure impartiality of decisions, all members of the <u>TUEC</u> must sign a conflict of interest and confidentiality declaration. (Aa template declaration is available on *WADA*'s website).
- 5.4 5.3Each National Anti-Doping Organization, International Federation and Major Event Organization must establish a clear process for applying to its <u>TUEC</u> for a <u>TUE</u> that complies with the requirements of this International Standard. It must also publish details of that process by (at a minimum) posting the information in a conspicuous place on its website and sending the information to WADA. WADA may re-publish the same information on its own website.
- 5.5 5.4Each National Anti-Doping Organization, International Federation and Major Event Organization must promptly report (in English or French) all decisions of its <u>TUEC</u> granting or denying TUEs, and all decisions to recognize or refusing to recognize other Anti-Doping Organizations' TUE decisions, through ADAMS or any other system approved by WADAas soon as possible and in any event within twenty-one (21) days of receipt of the decision. A decision to deny a TUE shall include an explanation of the reason(s) for the denial. In respect of TUEs granted, the information reported shall include (in English or French):
 - a) a.not only Whether the Athlete was permitted to apply for a TUE retroactively under Article 4.1 and an explanation of the reason(s) why, or whether the Athlete was permitted to apply for and was granted a TUE retroactively under Article 4.3 and an explanation of the reason(s) why;
 - <u>b)</u> <u>The</u> approved substance or method, <u>but also</u> the dosage(s), frequency—<u>and</u>, route of <u>Administration</u> permitted, the duration of the <u>TUE_(and, if different, the duration of prescribed treatment)</u>, and any conditions imposed in connection with the <u>TUE</u>; and
 - <u>c)</u> <u>b.theThe</u> *TUE* application form and the relevant clinical information (translated into-<u>English or French)</u> establishing that the Article <u>4.14.2</u> conditions have been satisfied in respect of such *TUE* (for access only by *WADA*, the *Athlete's National Anti-Doping Organization* and International Federation, and the *Major Event Organization* organizing an *Event* in which the *Athlete* wishes to compete).

[Comment to 5.4: The process of recognition of TUEs is greatly facilitated by use of ADAMS.]Article 5.5: The TUE application form may be translated into other languages by Anti-Doping Organizations, but the original English or French text must remain on the form, and an English or French translation of the content must be provided.

The full medical file, including diagnostic tests, laboratory results and values must be provided, but need not be translated into English or French. However, a translated summary of all the key information (including key diagnostic tests) must be entered into ADAMS, with sufficient information to clearly establish the diagnosis. It is strongly

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suggested that the summary be prepared by a physician or other person with adequate medical knowledge, in order to properly understand and summarize the medical information. More detailed/full translations may be required by the relevant Anti-Doping Organization or WADA, upon request.]

- 5.6 5.5When a National Anti-Doping Organization grants a TUE to an Athlete, it must warn him/her in writing (a) that that (a) the TUE is valid at national level only, and (b) that if the Athlete becomes an International-Level Athlete or competes in an International Event, that TUE will not be valid for those purposes unless it is recognized by the relevant International Federation or Major Event Organization in accordance with Article 7.17.0. Thereafter, the National Anti-Doping Organization should help the Athlete to determine when he/she needs to submit the TUE to an International Federation or Major Event Organization for recognition, and should guide and support the Athlete through the recognition process.
- 5.7 5.6Each International Federation and Major Event Organization must publish and keep updated a notice (at a minimum, by posting it in a conspicuous place on its website and sending it to WADA) that sets out clearly (1) which Athletes coming under its jurisdiction are required to apply to it for a TUE, and when; (2) which TUE decisions of other Anti-Doping Organizations it will automatically recognize in lieu of such application, in accordance with Article 7.1(a); and (3) which TUE decisions of other Anti-Doping Organizations will have to be submitted to it for recognition, in accordance with Article 7.1(b). WADA may re-publish the notice on its own website.
- 5.8 5.7Any TUE that an Athlete has obtained from and the Athlete subsequently becomes an International-Level Athlete or competes in an International Event, the TUE will not be valid unless and until the relevant International Federation recognizes that TUE in accordance with Article 7.0. Anylf an International Federation grants a TUE thatto an Athlete has obtained from an International Federation shall not be valid if and the Athlete then competes in an International Event organized by a Major Event Organization, the TUE will not be valid unless and until the relevant Major Event Organization recognizes that TUE in accordance with Article 7.0. As a result, if the International Federation or Major Event Organization (as applicable) declines to recognize that TUE, then (subject to the Athlete's rights of review and appeal) that TUE may not be relied upon to excuse the presence, Use, Possession or Administration of the Prohibited Substance or Prohibited Method mentioned in the TUE vis-à-vis that International Federation or Major Event Organization.

6.0 TUE Application Process

- 6.1 An Athlete who needs a TUE should apply as soon as possible. For substances prohibited In-Competition only, the Athlete should apply for a TUE at least thirty (30) days before his/hertheir next Competition, unless it is an emergency or exceptional situation.
- The Athlete should apply to his/hertheir National Anti-Doping Organization, International Federation and/or a Major Event Organization (as applicable), using the TUE application form provided. Anti-Doping Organizations shall make the application form they want Athletes to use available for download from their websites. That form must be based on the "TUE Application Form" template available on WADA's website. The template may be modified by Anti-Doping Organizations to include additional requests for information, but no sections or items may be removed.

[Comment to Article 6.2: In certain situations, an Athlete may not know which National Anti-

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Doping Organization they should apply to for a TUE. In such circumstances, the Athlete should consult the National Anti-Doping Organization of the country of the sport organization for which they compete (or with which they are a member or license holder), to determine if they fall within that National Anti-Doping Organization's TUE jurisdiction, according to their rules.

If that National Anti-Doping Organization refuses to evaluate the TUE application because the Athlete does not fall within its TUE jurisdiction, the Athlete should consult the anti-doping rules of the National Anti-Doping Organization of the country in which they reside (if different).

If the Athlete still does not fall within that National Anti-Doping Organization's TUE jurisdiction, the Athlete should then consult the anti-doping rules of the National Anti-Doping Organization of their country of citizenship (if different from where they compete or reside).

Athletes may contact any of the above-referenced National Anti-Doping Organizations for assistance with determining whether the National Anti-Doping Organization has TUE jurisdiction. In the event that none of the above-mentioned National Anti-Doping Organizations have TUE jurisdiction, where there is an Adverse Analytical Finding, the Athlete should ordinarily be permitted to apply for a retroactive TUE from the Anti-Doping Organization that has Results Management authority. See also the summary flowcharts on "Where to Apply?" in the medical section of WADA's website.]

- An Athlete may not apply to more than one (1) Anti-Doping Organization for a TUE for the Use of the same Prohibited Substance or Prohibited Method for the same medical condition. Nor may an Athlete have more than one (1) TUE at a time for the Use of the same Prohibited Substance or Prohibited Method for the same medical condition (and any such new TUE will supersede the previous TUE, which should be cancelled by the relevant Anti-Doping Organization).
- **6.2** The Athlete should submit the TUE application form to the relevant Anti-Doping Organization via ADAMS or as otherwise specified by the Anti-Doping Organization. The form must be signed by the treating physician and accompanied by:

a.a statement by an appropriately qualified physician, attesting to the need for the Athlete to Use the Prohibited Substance or Prohibited Method in question for Therapeutic reasons; andb. a comprehensive medical history, including documentation from the original diagnosing physician(s) (where possible) and

the results of all examinations, laboratory investigations and imaging studies relevant to the application.

[Comment to 6.2(b) Article 6.4: The information submitted in relation to the diagnosis, and treatment and duration of validity should be guided by the relevant WADA documents titled "Medical Information to Support the Decisions of TUECs" posted on WADA's website.]

- **6.5 6.3**The *Athlete* should keep a complete copy of the *TUE* application form and of all materials and information submitted in support of that application.
- 6.6 6.4A TUE application will only be considered by the <u>TUEC</u> following the receipt of a properly completed application form, accompanied by all relevant documents. Incomplete

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applications will be returned to the *Athlete* for completion and re-submission.

- **6.5** The <u>TUEC</u> may request from the *Athlete* or <u>his/hertheir</u> physician any additional information, examinations or imaging studies, or other information that it deems necessary in order to consider the *Athlete's* application; and/or it may seek the assistance of such other medical or scientific experts as it deems appropriate.
- **6.6** Any costs incurred by the *Athlete* in making the *TUE* application and in supplementing it as required by the <u>TUEC</u> are the responsibility of the *Athlete*.
- 6.9 6.7The <u>TUEC</u> shall decide whether or not to grant the application as soon as possible, and usually (i.e., unless exceptional circumstances apply) within no more than <u>twenty-one</u> (21) days of receipt of a complete application. Where a <u>TUE</u> application is made <u>in</u> a reasonable time prior to an <u>Event</u>, the <u>TUEC</u> must use its best endeavors to issue its decision before the start of the <u>Event</u>.
- **6.10 6.8**The <u>TUEC</u>'s decision must be communicated in writing to the *Athlete* and must be made available to *WADA* and to other *Anti-Doping Organizations* via *ADAMS*-or any other system approved by *WADA*, in accordance with Article **5.35.5**.
 - a.A decision to grant a *TUE* must specify the dosage(s), frequency, route and duration of *Administration* of the *Prohibited Substance* or *Prohibited Method* in question that the <u>TUEC</u> is permitting, reflecting the clinical circumstances, as well as any conditions imposed in connection with the *TUE*.
 - b.A decision to deny a *TUE* application must include an explanation of the reason(s) for the denial.
- 6.11 6.9 Each TUE will have a specified duration, as decided by the <u>TUEC</u>, at the end of which the TUE will expire automatically. If the Athlete needs to continue to Use the Prohibited Substance or Prohibited Method after the expiry date, he/she must submit an application for a new TUE well in advance of that expiry date, so that there is sufficient time for a decision to be made on the application before the expiry date.

[Comment to 6.9: The Article 6.11: Where applicable, the duration of validity should be guided by the WADA documents titled "Medical Information to Support the Decisions of TUECsTUE Physician Guidelines".]

- **6.12 6.10** A *TUE* will be withdrawn prior to expiry if the *Athlete* does not promptly comply with any requirements or conditions imposed by the *Anti-Doping Organization* granting the *TUE*. Alternatively a *TUE* may be reversed upon review by *WADA* or on appeal.
- **6.13 6.11**Where an Adverse Analytical Finding is issued shortly after a TUE for the Prohibited Substance in question has expired or has been withdrawn or reversed, the Anti-Doping Organization conducting the initial review of the Adverse Analytical Finding (Code, in accordance with Article 7.2)5.1.1.1 of the International Standard for Results Management shall consider whether the finding is consistent with Use of the Prohibited Substance prior to the expiry,

withdrawal or reversal of the *TUE*. If so, such *Use* (and any resulting presence of the *Prohibited Substance* in the *Athlete's Sample*) is not an anti-doping rule violation.

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6.14 6.12In the event that, after his/hertheir TUE is granted, the Athlete requires a materially different dosage, frequency, route or duration of Administration of the Prohibited Substance or Prohibited Method to that specified in the TUE, he/she must contact the relevant Anti-Doping Organization, who will then determine whether the Athlete needs to apply for a new TUE. If the presence, Use, Possession or Administration of the Prohibited Substance or Prohibited Method is not consistent with the terms of the TUE granted, the fact that the Athlete has the TUE will not prevent the finding of an anti-doping rule violation.

[Comment to Article 6.14: It is recognized that for certain medical conditions, dosages may fluctuate, particularly during the early stages of the establishment of a treatment regime or for a condition such as insulin-dependent diabetes. Such potential fluctuations should be accounted for in the TUE. However, in the event of a change that is not accounted for in the TUE, the Athlete must contact the relevant Anti-Doping Organization to determine whether a new TUE is required.]

7.0 TUE Recognition Process

- 7.1 Code Article 4.4 requires Anti-Doping Organizations to recognize TUEs granted by other Anti-Doping Organizations that satisfy the Article 4.14.2 conditions. Therefore, if an Athlete who becomes subject to the TUE requirements of an International Federation or Major Event Organization already has a TUE, he/she should not submit an application for a new TUE to the International Federation or Major Event Organization. Instead:
 - a. The International Federation or *Major Event Organization* may publish notice that it will automatically recognize *TUE* decisions made pursuant to *Code* Article 4.4 (or certain categories of such decisions, e.g., those made by specified *Anti-Doping Organizations*, or those relating to particular *Prohibited Substances*), provided that such *TUE* decisions have been reported in accordance with Article 5.3 and therefore are available for review by *WADA*5.5. If the *Athlete's TUE* falls into a category of *TUEs* that are automatically recognized in this way at the time the *TUE* is granted, he/she does not need to take any further action.

[Comment to Article_7.1(a): To ease the burden on Athletes, automatic recognition of TUE decisions once they have been reported in ADAMS in accordance with Article 5.35.5 is strongly encouraged. If an International Federation or Major Event Organizer is not willing to grant automatic recognition of all such decisions, it should grant automatic recognition of as many such decisions as possible, e.g., by publishing and keeping updated a list of Anti-Doping Organizations whose TUE decisions it will recognize automatically, and/or a list of those Prohibited Substances for which it will automatically recognize TUEs. Publication should be in the same manner as is set out in Article 5.35.4, i.e., the notice should be posted on the International Federation's website and sent to WADA and to National Anti-Doping Organizations.]

b. In the absence of such automatic recognition, the Athlete shall submit a request for recognition of the TUE to the International Federation or Major Event Organization in question, either via ADAMS or as otherwise specified by that International Federation or Major Event Organization. The request should be accompanied by a copy of the TUE

and the original *TUE* application form and supporting materials referenced at Articles
6.1 and 6.2 Article 6.4 (unless the Anti-Doping Organization that granted the *TUE* has already made the *TUE* and supporting materials available via ADAMS or other

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system approved by WADA, in accordance with Article 5.35.5).

- 7.2 Incomplete requests for recognition of a *TUE* will be returned to the *Athlete* for completion and re-submission. In addition, the <u>TUEC</u> may request from the *Athlete* or <u>his/hertheir</u> physician any additional information, examinations or imaging studies, or other information that it deems necessary in order to consider the *Athlete's* request for recognition of the *TUE*; and/or it may seek the assistance of such other medical or scientific experts as it deems appropriate.
- **7.3** Any costs incurred by the *Athlete* in making the request for recognition of the *TUE* and in supplementing it as required by the <u>TUEC</u> are the responsibility of the *Athlete*.
- 7.4 The <u>TUEC</u> shall decide whether or not to recognize the *TUE* as soon as possible, and usually (i.e., unless exceptional circumstances apply) within no more than <u>twenty-one</u> (21) days of receipt of a complete request for recognition. Where the request is made a reasonable time prior to an *Event*, the <u>TUEC</u> must use its best endeavors to issue its decision before the start of the *Event*.
- 7.5 The <u>TUEC</u>'s decision will be notified in writing to the *Athlete* and will be made available to *WADA* and to other *Anti-Doping Organizations* via *ADAMS* or any other system approved by *WADA*. A decision not to recognize a *TUE* must include an explanation of the reason(s) for the non-recognition.
- If an International Federation chooses to test an Athlete who is not an International-Level

 Athlete, it must recognize a TUE granted by that Athlete's National Anti-Doping

 Organization unless the Athlete is required to apply for recognition of the TUE pursuant to

 Articles 5.8 and 7.0, i.e. because the Athlete is competing in an International Event.

8.0 Review of *TUE* Decisions by *WADA*

- 8.1 Code Article 4.4.6 provides that WADA, in certain cases, must review TUE decisions of International Federations, and that it may review any other TUE decisions, in each case to determine compliance with the Article 4.1 and 4.2 conditions. In relation to the Article 4.2 conditions, WADA shall establish a WADA TUEC that meets the requirements of Article 5.25.3 to carry out such reviews. In relation to the Article 4.1 conditions, these can be reviewed by WADA (which may, at its discretion, consult with a member(s) of a WADA TUEC).
- 8.2 Each request for review must be submitted to WADA in writing, and must be accompanied by payment of the application fee established by WADA, as well as copies of all of the information specified in Article 6.26.4 (or, in the case of review of a TUE denial, all of the information that the Athlete submitted in connection with the original TUE application). The request must be copied to the partyAnti-Doping Organization whose decision would be the subject of the review, and to the Athlete (if he/she is not requesting the review).
- 8.3 Where the request is for review of a *TUE* decision that *WADA* is not obliged to review, *WADA* shall advise the *Athlete* as soon as practicable following receipt of the request whether or not it will referreview the *TUE* decision to the <u>WADA</u> TUEC for review. If <u>WADA</u> decides not to refer the <u>TUE</u> decision, it will return the application fee to the *Athlete*. Any decision by *WADA* not to referreview the *TUE* decision to the <u>WADA</u> TUEC is final and may not be appealed. However, the *TUE* decision may still be appealable, as set out in *Code* Article 4.4.7.



8.4 Where the request is for review of a *TUE* decision of an International Federation that *WADA* is obliged to review, *WADA* may nevertheless refer the decision back to the International Federation (a) for clarification (for example, if the reasons are not clearly set out in the decision); and/or (b) for re-consideration by the International Federation (for example, if the *TUE* was only denied because medical tests or other information required to demonstrate satisfaction of the Article 4.14.2 conditions were missing).

[Comment to Article 8.4: If an International Federation refuses to recognize a TUE granted by a National Anti-Doping Organization only because medical tests or other information required to demonstrate satisfaction of the Article 4.2 conditions are missing, the matter should not be referred to WADA. Instead, the file should be completed and re-submitted to the International Federation.1

- **8.5** Where a request for review is referred to the <u>WADA TUEC</u>, the <u>WADA TUEC</u> may seek additional information from the *Anti-Doping Organization* and/or the *Athlete*, including further studies as described in Article <u>6.56.7</u>, and/or it may obtain the assistance of other medical or scientific experts as it deems appropriate.
- **The** WADA_TUEC shall reverse any grant of a TUE that does not comply with the Article 4.1 and 4.2 conditions (as applicable). Where the TUE reversed was a prospective TUE (rather than a retroactive TUE), such reversal shall take effect upon the date specified by WADA (which shall not be earlier than the date of WADA's notification to the Athlete). The reversal shall not apply retroactively and the Athlete's results prior to such notification shall not be Disqualified. Where the TUE reversed was a retroactive TUE, however, the reversal shall also be retroactive.
- **8.7** The WADA TUEC shall reverse any denial of a TUE where the TUE application met the Article 4.1 and
 - <u>4.2</u> conditions <u>(as applicable)</u>, i.e., it shall grant the *TUE*.
- 8.8 Where-the WADA_TUEC reviews a decision of an International Federation that has been referred to it pursuant to Code Article 4.4.3 (i.e., a mandatory review), it may require whichever Anti- Doping Organization "loses" the review (i.e., the Anti-Doping Organization whose view it does not uphold) (a) to reimburse the application fee to the party that referred the decision to WADA (if applicable); and/or (b) to pay the costs incurred by WADA in respect of that review, to the extent they are not covered by the application fee.
- **8.9** Where the WADA TUEC reverses a TUE decision that WADA has decided in its discretion to review, WADA may require the Anti-Doping Organization that made the decision to pay the costs incurred by WADA in respect of that review.
- **8.10** If applicable, WADA shall communicate the reasoned decision of the WADA TUEC promptly to the Athlete and to his/hertheir National Anti-Doping Organization and International Federation (and, if applicable, the Major Event Organization).

9.0 Confidentiality of Information

9.1 The collection, storage, processing, disclosure and retention Processing of Personal Information during the TUE process by Anti-Doping Organizations and WADA shall comply with the International Standard for the Protection of Privacy and Personal Information.

Anti-Doping Organizations shall ensure that they have a valid legal

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authority or basis for such Processing, in accordance with the *International Standard* for the Protection of Privacy and Personal Information and applicable laws.

- 9.2 AnAnti-Doping Organizations shall communicate in writing the following information to Athletes as well as any other relevant information in accordance with Article 7.1 of the International Standard for the Protection of Privacy and Personal Information in connection with an Athlete applying's application for the grant of a TUE or for recognition of a TUE-shall provide written consent:
 - a.for the transmission of all All information pertaining to the application will be transmitted to members of all <u>TUECs</u> with authority under this *International Standard* to review the file and, as required, other independent medical or scientific experts, and to all necessary staff (including WADA staff) involved in the management, review or appeal of *TUE* applications;
 - b) b.for the The Athlete's must authorize their physician(s) to release to the any relevant TUEC upon request any health information that the any such TUEC deems necessary in order to consider and determine the Athlete's application; and
- <u>c.for the The</u> decision on the application to the made available to all *Anti-Doping Organizations*

with *Testing* authority and/or results management <u>Results Management</u> authority over the <u>Athlete</u>.

[Comment to Article 9.2: Prior to collecting Personal Information or obtaining consent from an Athlete, the Anti-Doping Organization shall communicate to the Athlete the information set out in Article 7.1 of the International Standard for the Protection of Privacy and Personal InformationWhere Anti-Doping Organizations are relying upon the Athlete's consent to Process Personal Information in connection with the TUE process, the Athlete applying for the grant or recognition of a TUE shall provide written and explicit consent to the foregoing.]

- 9.3 The *TUE* application shall be dealt with in accordance with the principles of strict medical confidentiality. The members of the <u>TUEC, all relevant TUECs</u>, any consulted independent experts and the relevant staff of the *Anti-Doping Organization* shall conduct all of their activities relating to the process in strict confidence and shall sign appropriate confidentiality agreements. In particular, they shall keep the following information confidential:
- <u>a.</u> All medical information and data provided by the *Athlete* and physician(s) involved in the *Athlete*'s

care-: and

- **b.** All details of the application, including the name of the physician(s) involved in the process.
- 9.4 Should the *Athlete* wish to revoke the right of the TUEC to obtain any health information on his/hertheir behalf, the *Athlete* shall notify his/her medical practitionertheir physician in writing of such revocation; provided that, as a result of that revocation, the *Athlete's* application for a *TUE* or for recognition of an existing *TUE* will be deemed withdrawn

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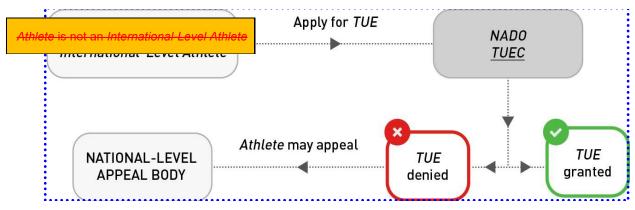


without approval/recognition having been granted.

9.5 Anti-Doping Organizations shall only use information submitted by an Athlete in connection with a TUE application to evaluate the application and in the context of potential anti-doping rule violation investigations and proceedings.

ANNEX 1: CODE ARTICLE 4.4 FLOW-CHART

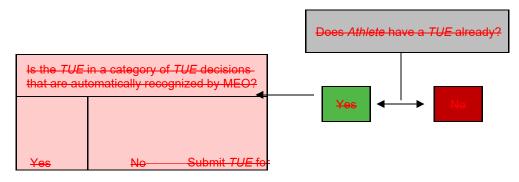
1. TUE procedure if Athlete is not an International-Level Athlete when need for TUE arises



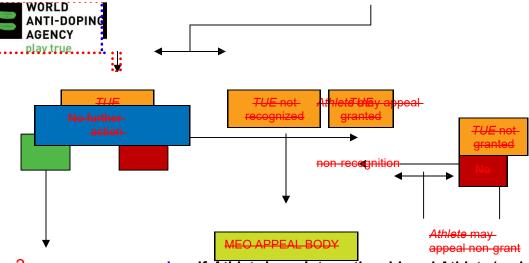
2. Apply for TUE



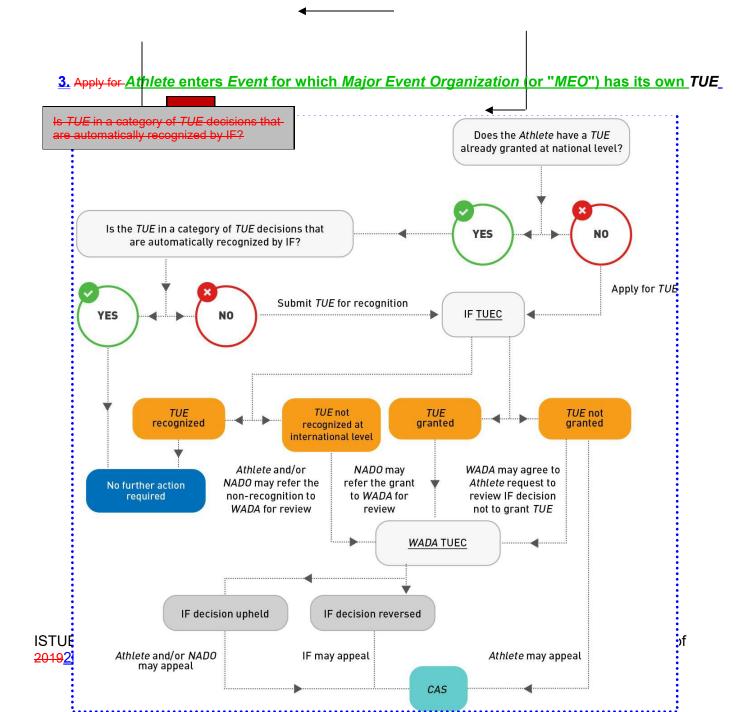
2. Athlete enters Event for which Major Event Organization (or "MEO") has its own TUE requirements

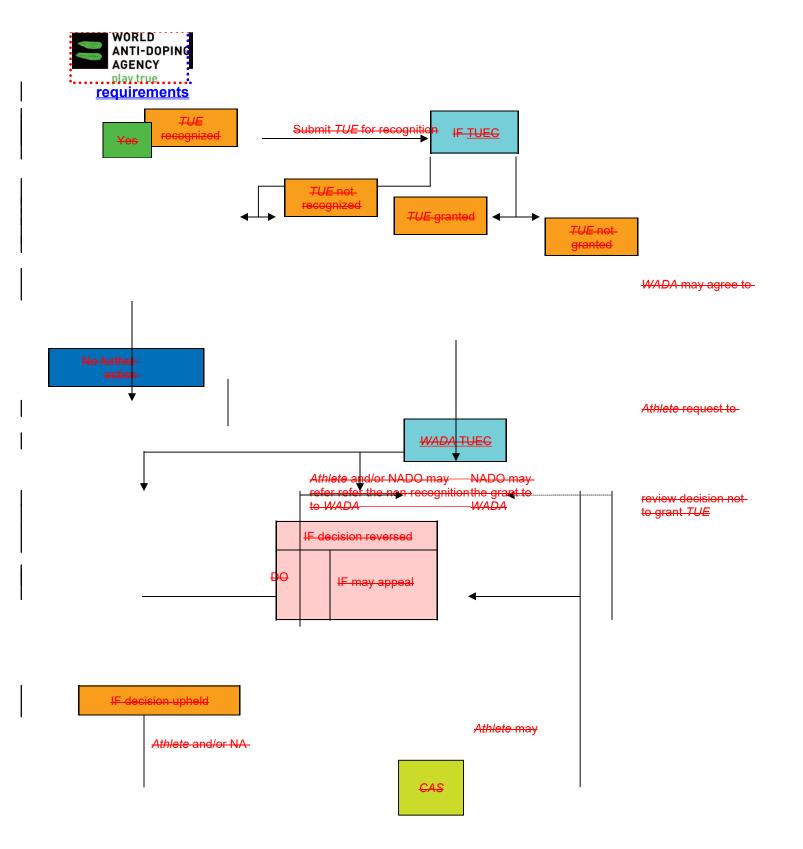


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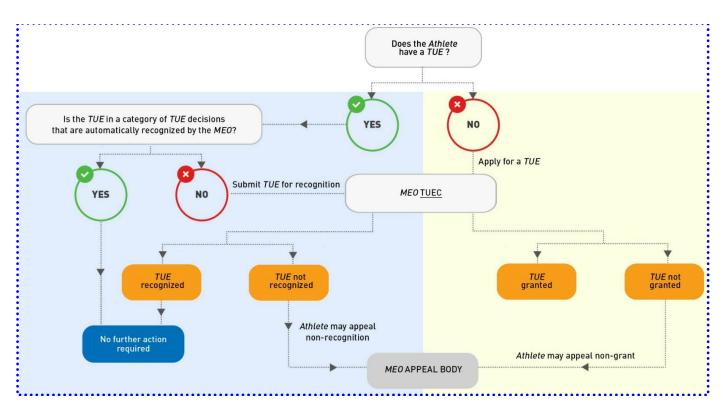


3.TUE Procedure procedure if Athlete is an International-Level Athlete (and so subject to the International Federation's TUE requirements) when need for TUE arises









Document comparison by Workshare 10.0 on Tuesday, May 26, 2020 10:34:31 AM

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Description	ISTUE - Current in force January 2019				
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