WORLD ANTI-DOPING CODE

INTERNATIONAL STANDARD



THERAPEUTIC USE EXEMPTIONS

JANUARY 2021

WORLD ANTI-DOPING AGENCY
play true

WORLD ANTI-DOPING AGENCY
play true

International Standard for *Therapeutic Use Exemptions*

The World Anti-Doping *Code International Standard* for *Therapeutic Use Exemptions* 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. It 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, the fifth effective January 2018, the sixth effective January 2019. A revised version was approved by the *WADA* Executive Committee at the World Anti-Doping Conference in Katowice on 7 November 2019 and is effective as of 1 January 2021.

Published by:

World Anti-Doping Agency
Stock Exchange Tower8
800 Place Victoria (Suite 1700)
PO Box 120
Montreal, Quebec
Canada H4Z 1B7

www.wada-ama.org

Tel: + 1 514 904 9232
Fax: + 1 514 904 8650
E-mail: code@wada-ama.org

WORLD ANTI-DOPING AGENCY
play true

TABLE OF CONTENTS

PART ONE: INTRODUCTION, *CODE* PROVISIONS, *INTERNATIONAL STANDARD* PROVISIONS AND DEFINITIONS 4

1.0 Introduction and Scope 4

2.0 *Code* Provisions 4

3.0 Definitions and Interpretation 4

PART TWO: STANDARDS AND PROCESS FOR GRANTING *TUEs* 10

4.0 Obtaining a *TUE* 10

5.0 *TUE* Responsibilities of *Anti-Doping Organizations* 12

6.0 *TUE* Application Process 15

7.0 *TUE* Recognition Process 17

8.0 Review of *TUE* Decisions by *WADA* 18

9.0 Confidentiality of Information 19

ANNEX 1: *Code* Article 4.4 Flow-Chart 21

WORLD ANTI-DOPING AGENCY
play true

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 italicized. Terms that are defined in this or another *International Standard* are underlined.

2.0 *Code* Provisions

The following articles in the 2021 *Code* are directly relevant to the *International Standard* for *Therapeutic Use Exemptions*, they can be obtained by referring to the *Code* itself:

- *Code* Article 4.4 *Therapeutic Use Exemptions ("TUEs")*
- *Code* Article 13.4 Appeals Relating to *TUEs*

3.0 Definitions and Interpretation

3.1 Defined terms from the 2021 *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 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, establishes in a *Sample* the presence of a *Prohibited Substance* or its *Metabolite*s or *Marker*s or evidence of the *Use* of a *Prohibited Method*.

***Anti-Doping Organization*:** *WADA* 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 *Event*s, International Federations, and *National Anti-Doping Organization*s.

***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* must be applied. For purposes of Article 2.8 and Article 2.9 and for purposes of anti-doping information and 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 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.]

***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 and 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, World Championships of an International Federation, or Pan American Games).

***In-Competition*:** The period commencing at 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-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: 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.]

***Major Event Organizations*:** The continental associations of *National Olympic Committee*s 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 *Sample*s, the management of test results, and the conduct of hearings 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.

***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: 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 them. 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 them. 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*.

***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 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: 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).

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

***Therapeutic Use Exemption [TUE]*:** A *Therapeutic Use Exemption* 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 Defined terms from the *International Standard* for the Protection of Privacy and Personal Information

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

[Comment to Personal Information: It is understood that Personal Information includes, but is not limited to, information relating to an Athlete's name, date of birth, contact details and sporting affiliations, whereabouts, designated TUEs (if any), anti-doping test results, and Results 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.]

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

3.3 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.

3.4.2 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.

3.4.3 The comments annotating various provisions of the *International Standard* for *Therapeutic Use Exemptions* shall be used to guide its interpretation.

3.4.4 Unless otherwise specified, references to Sections and Articles are references to Sections and Articles of the *International Standard* for *Therapeutic Use Exemptions*.

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.

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* for *Therapeutic Use Exemptions*.

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;

b) 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) 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);

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

e) The *Athlete Used Out-of-Competition*, for Therapeutic reasons, a *Prohibited Substance* that is only prohibited *In-Competition*.

[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.]

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

a) The *Prohibited Substance* or *Prohibited Method* in question is needed to treat a diagnosed medical condition supported by relevant clinical evidence.

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

b) The Therapeutic *Use* of the *Prohibited Substance* or *Prohibited Method* will not, on the balance of probabilities, produce any additional enhancement of performance beyond what might be anticipated by a return to the *Athlete's* normal state of health following the treatment of the medical condition.

[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.]

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

4.3 In exceptional circumstances and notwithstanding any other provision in this *International Standard* for *Therapeutic Use Exemptions*, an *Athlete* may apply for and be granted retroactive approval for his/her Therapeutic *Use* of a *Prohibited Substance* or *Prohibited Method* if, considering the purpose of the *Code*, it would be manifestly unfair not to grant a retroactive *TUE*. For *International-Level Athletes* and *National-Level Athletes*, an *Anti-Doping Organization* may grant an *Athlete's* application for a retroactive *TUE* 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* may grant an *Athlete's* application for a retroactive *TUE* pursuant to this Article without first consulting *WADA*; however, *WADA* may at any time review an *Anti-*

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

Any decision made by *WADA* and/or an *Anti-Doping Organization* under this Article 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.

[Comment to Article 5.1: See Annex 1 – Code Article 4.4 Flow-Chart for a flow-chart summarizing the key provisions of Code Article 4.4.

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.]

5.2 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 his/her *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*).

5.3 Each *National Anti-Doping Organization*, International Federation and *Major Event Organization* must establish a TUEC to consider whether applications for grant or recognition of *TUEs* meet the conditions set out in Article 4.2.

[Comment to 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 TUEC for this purpose, or rather whether it outsources the task by agreement to a third party. The aim in each case is to ensure that Athletes competing in such Events have the ability to obtain TUEs quickly and efficiently before they compete.]

a) TUECs should include at least three (3) physicians with experience in the care and treatment of *Athlete*s and a sound knowledge of clinical, sports and exercise medicine. In cases where specific expertise is required (for example, for *Athletes* with impairments where the substance or method pertains to the *Athlete's* impairment), at least one (1) TUEC member or expert should 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 TUEC must sign a conflict of interest and confidentiality declaration (a template declaration is available on *WADA's* website).

5.4 Each *National Anti-Doping Organization*, International Federation and *Major Event Organization* must establish a clear process for applying to its TUEC for a *TUE* 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 Each *National Anti-Doping Organization*, International Federation and *Major Event Organization* must promptly report (in English or French) all decisions of its TUEC granting or denying *TUEs*, and all decisions to recognize or refusing to recognize other *Anti-Doping Organizations' TUE* decisions, through *ADAMS* as 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) 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;

b) The approved substance or method, the dosage(s), frequency, route of *Administration* permitted, the duration of the *TUE* (and, if different, the duration of prescribed treatment), and any conditions imposed in connection with the *TUE*; and

c) The *TUE* application form and the relevant clinical information establishing that the Article 4.2 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 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 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 When a *National Anti-Doping Organization* grants a *TUE* to an *Athlete*, it must warn him/her in writing that (a) the *TUE* is valid at national level only, and (b) 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 7.0. 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 Each 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* 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).

5.8 If a *National Anti-Doping Organization* grants a *TUE* to an *Athlete* 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. If an International Federation grants a *TUE* to an *Athlete* 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/her next *Competition*, unless it is an emergency or exceptional situation.

6.2 The *Athlete* should apply to his/her *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-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 licence 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.]

6.3 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*).

6.4 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 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 Article 6.4: The information submitted in relation to the diagnosis and treatment should be guided by the relevant WADA documents posted on WADA's website.]

6.5 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 A *TUE* application will only be considered by the TUEC following the receipt of a properly completed application form, accompanied by all relevant documents. Incomplete applications will be returned to the *Athlete* for completion and re-submission.

6.7 The TUEC may request from the *Athlete* or his/her 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.

6.8 Any costs incurred by the *Athlete* in making the *TUE* application and in supplementing it as required by the TUEC are the responsibility of the *Athlete*.

6.9 The TUEC 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 twenty-one (21) days of receipt of a complete application. Where a *TUE* application is made in a reasonable time prior to an *Event*, the TUEC must use its best endeavors to issue its decision before the start of the *Event*.

6.10 The TUEC'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*, in accordance with Article 5.5.

6.11 Each *TUE* will have a specified duration, as decided by the TUEC, 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 Article 6.11: Where applicable, the duration of validity should be guided by the WADA documents titled "TUE Physician Guidelines".]

6.12 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 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*, in accordance with *Code* Article 7.2, 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.

6.14 In the event that, after his/her *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 4.2 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 5.5. 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 5.5 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 5.4, 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 6.4 (unless the *Anti-Doping Organization* that granted the *TUE* has already made the *TUE* and supporting materials available via *ADAMS*, in accordance with Article 5.5).

7.2 Incomplete requests for recognition of a *TUE* will be returned to the *Athlete* for completion and re-submission. In addition, the TUEC may request from the *Athlete* or his/her 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 TUEC are the responsibility of the *Athlete*.

7.4 The TUEC 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 twenty-one (21) days of receipt of a complete request for recognition. Where the request is made a reasonable time prior to an *Event*, the TUEC must use its best endeavors to issue its decision before the start of the *Event*.

7.5 The TUEC'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*. A decision not to recognize a *TUE* must include an explanation of the reason(s) for the non-recognition.

7.6 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 5.3 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 6.4 (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 *Anti-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 review the *TUE* decision. Any decision by *WADA* not to review the *TUE* decision 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 4.2 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.]

8.5 Where a request for review is referred to the *WADA* TUEC, the *WADA* TUEC may seek additional information from the *Anti-Doping Organization* and/or the *Athlete*, including further studies as described in Article 6.7, and/or it may obtain the assistance of other medical or scientific experts as it deems appropriate.

8.6 *WADA* 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 *WADA* shall reverse any denial of a *TUE* where the *TUE* application met the Article 4.1 and 4.2 conditions (as applicable), i.e., it shall grant the *TUE*.

8.8 Where *WADA* 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 *WADA* 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/her *National Anti-Doping Organization* and International Federation (and, if applicable, the *Major Event Organization*).

9.0 Confidentiality of Information

9.1 The Processing of Personal Information during the *TUE* process by *Anti-Doping Organizations* 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 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 *Anti-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's* application for the grant or recognition of a *TUE*:

a) All information pertaining to the application will be transmitted to members of all TUECs 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) The *Athlete* must authorize his/her physician(s) to release to any relevant TUEC upon request any health information that any such TUEC deems necessary in order to consider and determine the *Athlete's* application; and

c) The decision on the application will be made available to all *Anti-Doping Organizations* with *Testing* authority and/or *Results Management* authority over the *Athlete.*

[Comment to Article 9.2: Where 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 all relevant TUECs, 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:

a) All medical information provided by the *Athlete* and physician(s) involved in the *Athlete*'s care; and

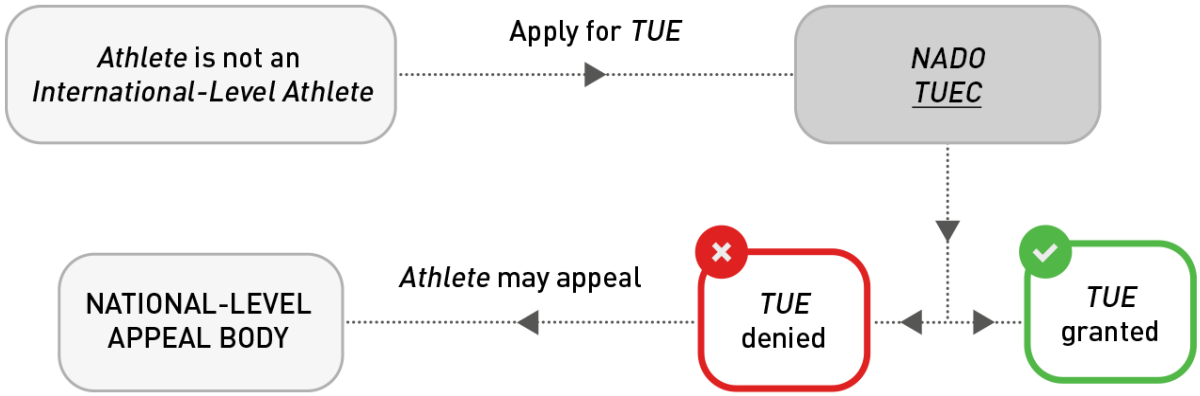
b) All details of the application, including the name of the physician(s) involved in the process.

9.4 Should the *Athlete* wish to revoke the right of a TUEC to obtain any health information on his/her behalf, the *Athlete* shall notify his/her 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 without approval/recognition having been granted.

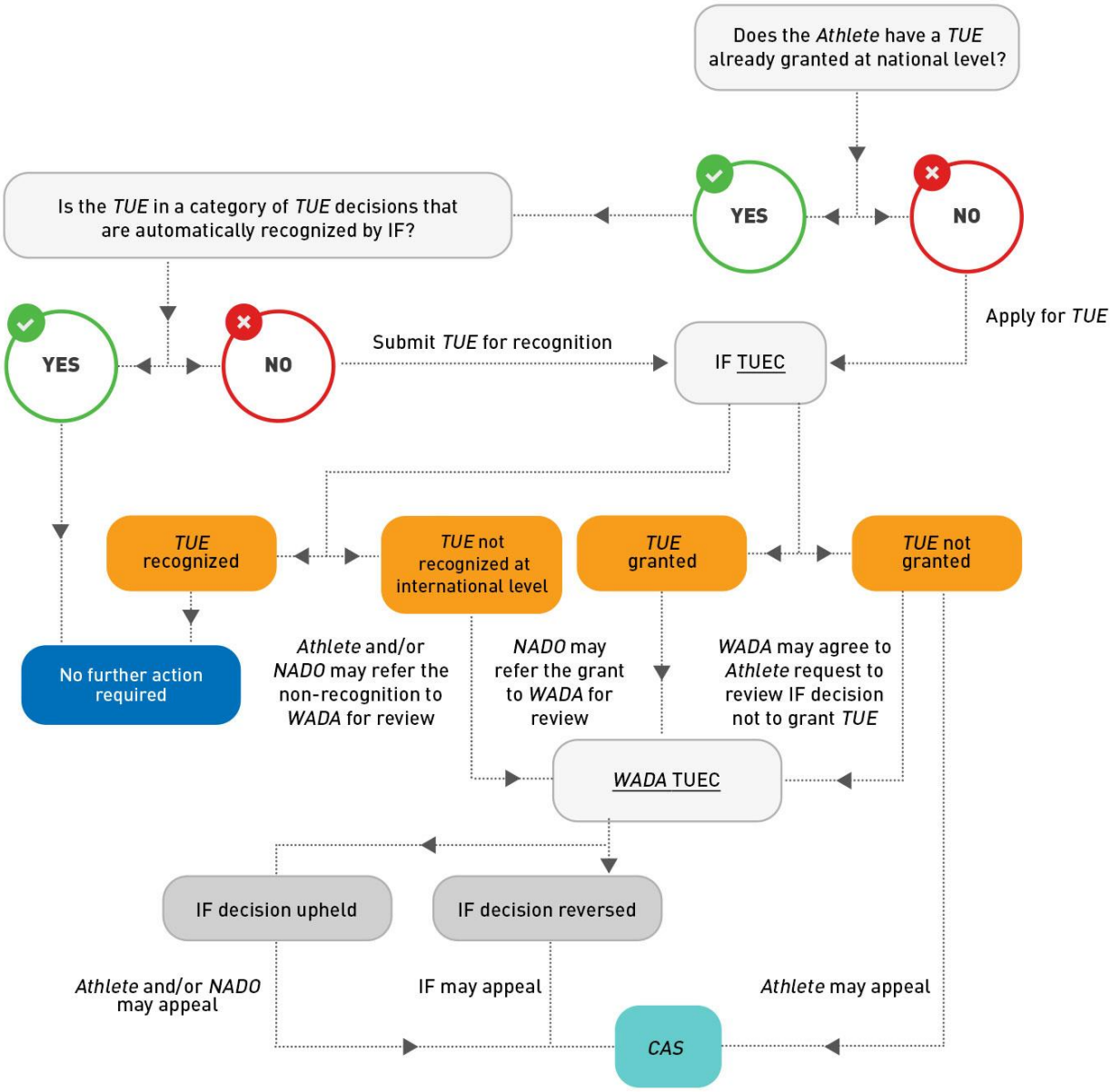
9.5 *Anti-Doping Organizations* shall only use information submitted by an *Athlete* in connection with a *TUE* application to evaluate the application and in the context of potential anti-doping rule violation investigations and proceedings.

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



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

