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ISTUE

Therapeutic Use Exemptions Guidelines

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Table of Contents

1.0	Introduction	4
1.1	Scope.....	4
1.2	References.....	5
1.2.1	Defined Terms	5
1.2.2	Documentation.....	5
1.2.3	TUE Procedure Flow Charts	5
2.0	Criteria for Granting a TUE	6
3.0	Application Process	7
3.1	Submission Timing and Deadline	7
3.1.1	Forms	7
3.1.2	Medical Information.....	8
3.2	Submitting the Application.....	8
3.3	Approval.....	8
3.4	Commencement of Medical Treatment.....	8
3.5	Documentation Criteria.....	9
3.6	Incomplete Applications	9
3.7	Requests for Further Information.....	9
3.8	Costs.....	10
4.0	Confidentiality of Information	10
5.0	Duration of TUE Validity	11
5.1	Chronic Conditions.....	11
5.2	Changes in the TUE.....	12
6.0	TUE Renewal	12
6.1	Renewal Requirements.....	12
6.2	Renewal Option in ADAMS	12
6.3	No Automatic Renewals	12
7.0	Retroactive TUEs	12
7.1	Further Clarification on Retroactive TUEs	13

8.0	ADO Authority and TUE Recognition	14
8.1	ADO Authority to Grant a TUE	14
8.1.1	NADOs	14
8.1.2	IFs and MEOs.....	15
8.1.3	Change in Athlete’s Competition Level.....	15
8.2	TUE Recognition	15
9.0	TUE Review and Appeal Processes	16
10.0	ADO TUEC Responsibilities	18
10.1.1	Conflict of Interest and Confidentiality	20
10.2	21-Day Deadline for Decisions.....	20
10.2.1	Failure to Meet Deadline	20
11.0	WADA TUE Monitoring and Review	21
11.1	WADA TUE Review	21
11.2	TUE Status During WADA Review	23
11.3	Appeal of WADA Decisions.....	23
12.0	TUE Management Within ADAMS	24
12.1	ADAMS and Athletes	25
12.2	ADAMS and Physicians	25
12.3	ADAMS and ADOs.....	25
13.0	Definitions	26
13.1	2015 Code Defined Terms	26
13.2	ISTUE Defined Terms.....	31
13.3	ISTI Defined Terms.....	31
13.4	ISL Defined Terms.....	32
13.5	ISPPPI Defined Terms.....	32

1.0 Introduction

The International Standard for Therapeutic Use Exemptions (ISTUE) was created with the understanding that, due to illness or medical condition, an *Athlete* may require the *Use* of medications or treatments on the World Anti-Doping Agency's (WADA's) *Prohibited List*.

The 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 Substance* or *Prohibited Method* shall not be considered an anti-doping rule violation (ADRV) if it is consistent with the provisions of a Therapeutic Use Exemption (*TUE*) granted in accordance with the ISTUE (*Code Article 4.4.1*).

A *TUE* is granted to an *Athlete* under narrow, well-defined conditions. The *TUE* enables the *Athlete* to take the necessary medication while competing in sport *Events*, without resulting in a doping offence.

The *Athlete* must have a well-documented medical condition, backed up by reliable, relevant and sufficient medical data (ISTUE Article 6.2) that demonstrates he/she meets the criteria for grant of a *TUE*. This mandatory documentation supports the *Athlete's TUE* application to his/her relevant *Anti-Doping Organization (ADO)*.

1.1 Scope

This *TUE* Guidelines document takes *ADOs* through the lifecycle of the *TUE*, starting with the criteria for granting a *TUE*.

The Guidelines bring forward key *ADO* responsibilities, including support of *Athletes* making *TUE* applications, recognition of *TUEs*, and communication of *TUE* decisions. Confidentiality provisions and WADA's role in the review of *TUE* decisions are also addressed.

These Guidelines are not mandatory, but are intended to give clarity and additional guidance to *Code Article 4.4* and the ISTUE, each of which is mandatory.

Code Article 4.4 and the ISTUE prevail should any differences or ambiguities with the *TUE* Guidelines arise. The comments annotating various provisions of the ISTUE shall be used to interpret that *International Standard (IS)*.

1.2 References

1.2.1 Defined Terms

These *TUE* Guidelines include defined terms from the *Code*, ISTUE, International Standard for Testing and Investigations (ISTI), International Standard for Laboratories (ISL) and the International Standard for the Protection of Privacy and Personal Information (ISPPPI). *Code* terms are written in italics. Terms from the *IS* are underlined.

These definitions are listed in Guidelines Section 13.

1.2.2 Documentation

The following are considered as main references for the *TUE*, all of which are available on WADA's Web site: www.wada-ama.org.

- 2015 World Anti-Doping Code
- International Standard for Therapeutic Use Exemptions
- Questions and Answers on Therapeutic Use Exemptions
- Medical Information to Support the Decisions of Therapeutic Use Exemption Committees (*TUE* Physician Guidelines)
- Results Management, Hearings and Decisions Guidelines

1.2.3 *TUE* Procedure Flow Charts

The flow charts in Annex 1 visually represent *Code* Article 4.4 *TUE* procedures for:

1. *Athletes* who are not *International-Level Athletes*.
2. *International-Level Athletes*.
3. *Major Event Organizations (MEOs)* with their own requirements.

2.0 Criteria for Granting a TUE

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

- a. The *Prohibited Substance* or *Prohibited Method* in question is needed to treat an acute or chronic medical condition, such that the *Athlete* would experience a significant impairment to health if the *Prohibited Substance* or *Prohibited Method* were to be withheld (ISTUE Article 4.1(a)).
- b. The Therapeutic Use of the *Prohibited Substance* or *Prohibited Method* is highly unlikely to 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 acute or chronic medical condition (ISTUE Article 4.1(b)).

Although there may be some enhancement of individual performance as a result of the efficacy of the treatment, nevertheless, such enhancement must not exceed the level of performance of the *Athlete* prior to the onset of his/her medical condition.

- c. There is no reasonable Therapeutic alternative to the *Use* of the *Prohibited Substance* or *Prohibited Method* (ISTUE Article 4.1(c)).

Three points should be noted in relation to reasonable Therapeutic alternatives:

- Only valid and referenced medications are to be considered as alternatives.
 - The definition of what is valid and referenced may vary from one country to another. These differences should be taken into account. For example, a medication may be registered in one country and not in another, or approval may be pending, etc.
 - There may be instances where it is not medically appropriate to try the alternatives before *Using* the medication containing the *Prohibited Substance*. In these cases, the physician is to state why.
- d. The necessity for the *Use* of the *Prohibited Substance* or *Prohibited Method* is not due, wholly or in part, to prior *Use* (without a TUE) of a substance or method that was prohibited at the time of such *Use* (ISTUE Article 4.1 d).

When a TUEC is deciding whether or not to recognize a TUE granted by another Anti-Doping Organization (see Section 8.2, below), and when WADA is reviewing a decision to grant (or not to grant) a TUE (see Section 11.1, below), the issue will be

the same as it is for a TUEC that is considering an application for a TUE under Section 3, below, i.e., has the Athlete demonstrated by a balance of probability that each of the conditions set out in article 4.1 is met?

WADA documents titled “Medical Information to Support the Decisions of TUECs” (*TUE Physician Guidelines*) assist physicians and ADOs in applying these criteria to particular medical conditions. These documents are available on WADA’s Web site www.wada-ama.org.

3.0 Application Process

A *TUE* is required for all treatments involving the *Use of a Prohibited Substance or Method* on the *Prohibited List*.

An *Athlete* must obtain a *TUE* prior to *Using* or *Possessing* the substance or method in question (ISTUE Article 4.2), unless one of the exceptions set out in ISTUE Article 4.3 applies. (Also see Guidelines Section 7.0 on Retroactive *TUEs*.)

3.1 Submission Timing and Deadline

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 30 days before his/her next *Competition*, unless it is an emergency or exceptional situation (ISTUE Articles 4.3 and 6.1). If the *Athlete* knows he/she will be taking a substance on a long-term basis, even if it is only prohibited *In-Competition*, he/she should still apply as soon as possible to the appropriate *ADO*.
- **For substances prohibited at all times:** The *TUE* application must be submitted as soon as the medical condition requiring the *Use of a Prohibited Substance or Prohibited Methods* is diagnosed. If the condition is diagnosed before the *Athlete* becomes subject to anti-doping rules prohibiting the *Use of Prohibited Substances and Prohibited Methods*, he/she should submit a *TUE* application as soon as he/she becomes subject to those rules, unless he/she is one of those *Athletes* competing only at national level or below who is permitted by his/her *NADO* to apply (if necessary) for a retroactive *TUE* (ISTUE 4.3(c)).

3.1.1 Forms

All forms customized by *ADOs* should be in English or French, and any national language(s) that may be used. All copies of applications sent to *WADA* must be in English or French, or a translation into English or French must be provided (ISTUE Article 5.4).

ADOs must use the *TUE* application template provided in ISTUE Annex 2, adding their logo and contact details, and providing the form on their Web site for download by *Athletes*.

Additional requests for information may be added, but no sections or items may be removed (ISTUE Article 6.1). It is important that all requests for information stipulated by *WADA* remain on the forms.

3.1.2 Medical Information

All appropriate medical information necessary for the decision must be submitted in English or French. Files received by the *ADO* that are not in either English or French must be translated prior to being sent to *WADA*.

Note that it is not necessary to translate all the medical documents. However, a summary that explains the diagnosis and key elements of the clinical exams, medical tests and treatment plan is required.

3.2 Submitting the Application

The *Athlete* applies to his/her *National Anti-Doping Organization (NADO)*, *International Federation (IF)* or *MEO* as applicable (*Code Article 4.4*), using the *TUE* application form available for download on the *ADO's* Web site (ISTUE Article 6.1).

The *Athlete submits* his/her *TUE* application to the *ADO* via *WADA's* Anti-Doping Administration and Management System (*ADAMS*) or in paper format using the appropriate *TUE* form. In the latter case, the *ADO* then enters the information in *ADAMS*.

3.3 Approval

TUE applications are examined by the Therapeutic Use Exemption Committee (TUEC) of the relevant *ADO*.

TUEC decisions should normally be taken within 21 days of receipt of all of the necessary documentation, and should be communicated in writing to the *Athlete* by the relevant *ADO* (ISTUE Articles 6.7 and 6.8).

3.4 Commencement of Medical Treatment

The *TUE* is effective upon receipt of notification from the relevant *ADO* that the *TUE* has been granted.

Athletes Using the Prohibited Substance or Prohibited Method prior to receiving notification of *TUE* authorization do so at their own risk.

Such *Use* would constitute an **anti-doping rule violation in the event of denial of the *TUE* by the TUEC**. However, in situations of a true medical emergency, an *Athlete's* health should never be put in jeopardy for administrative reasons. See Guidelines Section 7.0 on Retroactive *TUEs*.

3.5 Documentation Criteria

A *TUE* application is deemed complete if it enables the TUEC to determine if the criteria set forth in the ISTUE are satisfied.

The following supporting documents must be attached to the completed *TUE* application form:

- A **statement by an appropriately qualified physician**, attesting to the *Athlete's* diagnosis and need to *Use the Prohibited Substance or Prohibited Method* in question for Therapeutic reasons (ISTUE Article 6.2(a)); and
- 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 (ISTUE Article 6.2(b)).

See "Medical Information to Support the Decisions of TUECs" (*TUE* Physician Guidelines) for support documentation requirements.

Athletes should keep a complete copy of the *TUE* application form, and of all materials and information submitted in support of that application (ISTUE Article 6.3).

3.6 Incomplete Applications

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 (ISTUE Article 6.4).

3.7 Requests for Further Information

The TUEC may request additional information, examinations or imaging studies, or other information from the *Athlete* or his/her physician, and/or involve other medical or scientific experts (ISTUE Article 6.5).

Similarly, in its *TUE* review, the WADA TUEC may request additional information from the *ADO* and/or the *Athlete*, including further studies, and/or involve other medical or scientific experts (ISTUE Articles 6.5 and 8.5). See Guidelines Section 12.1.

However, it should be noted that the WADA TUEC may reverse a granted *TUE* without requesting further information, and the *Athlete* would then have to re-apply for a *TUE* to the appropriate *ADO*.

3.8 Costs

The *Athlete* is responsible for all costs related to the *TUE* application, *TUE* recognition requests, and for any supplemental information required by the TUEC (ISTUE Article 6.6).

4.0 Confidentiality of Information

Collection, storage, processing, disclosure, and retention of Personal Information by *ADOs* and *WADA* during the *TUE* process shall comply with ISPPPI criteria (ISTUE Article 9.1).

An *Athlete* applying for a *TUE* or for *TUE* recognition shall provide written consent for the following:

- a. Transmission of all information pertaining to the application to all TUEC members authorized 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. Release by the *Athlete's* physician(s) upon TUEC request of any health information deemed necessary by the TUEC to consider and determine the *Athlete's* application; and
- c. Decision on the application be made available to all *ADOs* with Testing Authority and/or Results Management Authority (RMA) over the *Athlete*.

Before collecting Personal Information or obtaining consent from an *Athlete*, the *ADO* shall communicate to the *Athlete* the information set out in ISPPPI Article 7.1.

Athletes applying for a *TUE* through *ADAMS* will be presented with the above-mentioned consents within *ADAMS*.

TUE applications are managed according to the principles of strict medical confidentiality. TUEC members, independent experts and the relevant *ADO* staff shall conduct all activities relating to the process in strict confidence, and sign appropriate confidentiality agreements.

To revoke the TUEC's right to obtain any health information on his/her behalf, the *Athlete* shall notify his/her medical practitioner in writing. Upon revocation, the *Athlete's* application for a *TUE* or for recognition of an existing *TUE* will be considered withdrawn without approval/recognition granted.

Information submitted by an *Athlete* should only be used by *ADOs* for the purpose of evaluating a *TUE* request and in the context of potential *ADRV* investigations and procedures.

5.0 Duration of *TUE* Validity

The TUEC assigns each *TUE* a start and end date, upon which the *TUE* expires automatically. If the *Athlete* needs to continue to Use the *Prohibited Substance* or *Prohibited Method* after the specified end date, he/she must apply for a new *TUE* well in advance, to allow sufficient time for a decision to be made on the application before the existing *TUE* expires (ISTUE Article 6.9).

For guidance on *TUE* duration, consult the *WADA* documents titled "Medical Information to Support the Decisions of TUECs" (*TUE* Physician Guidelines).

A *TUE* will be withdrawn prior to expiry if the *Athlete* does not promptly comply with any requirements or conditions imposed by the *ADO* granting the *TUE*. Alternatively, a *TUE* may be reversed upon review by *WADA* or on appeal (ISTUE Article 6.10).

An *MEO TUE* may only be granted for the duration of the *Event*. If the *Athlete* needs to continue to Use the *Prohibited Substance* or *Prohibited Method* in question after the *Event*, he/she must apply to his/her *IF* or *NADO* for a new *TUE* — unless he/she competes below national level, or competes only at national level and his/her *NADO* permits the making of retroactive applications (ISTUE Article 4.3).

5.1 Chronic Conditions

A *TUE* for an otherwise *Prohibited Substance* or *Prohibited Method* will always be granted for a specific dose, frequency, method, route, and duration of *Administration*, even if the medical condition and the Use of the substance are chronic. When a potentially chronic medical condition is first diagnosed, it may be advisable to grant a *TUE* for a shorter period until the medical regime is stabilized. In certain situations, a (clearly defined) range of dosage may be acceptable.

For some chronic conditions, a *TUE* may be granted for a prolonged period. See "Medical Information to Support the Decisions of TUECs" (*TUE* Physician Guidelines). Nevertheless, independent of *TUE* requirements, the Use of the substance should be regularly monitored by a physician as part of good medical practice.

5.2 Changes in the *TUE*

Under ISTUE Article 6.12, if the *Athlete* subsequently 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 apply for a new *TUE*.

If the presence, *Use*, *Possession* or *Administration* of the *Prohibited Substance* or *Prohibited Method* is inconsistent with the terms of the *TUE* granted, the fact that the *Athlete* has a *TUE* will not prevent an ADRV finding.

6.0 *TUE* Renewal

6.1 Renewal Requirements

TUEs cannot be renewed without a new medical consultation and confirmation. The *Athlete* must complete a new application signed by his/her physician when the previous *TUE* expires.

6.2 Renewal Option in *ADAMS*

ADAMS simplifies the *TUE* renewal procedure by providing a computerized form in which a majority of the fields are already completed.

The *Athlete* obtains and submits the updated medical documentation, following the standard *TUE* application procedure. Application forms should be completed, signed and dated by the physician and the *Athlete*, whether this is the *Athlete's* first *TUE* application or an application for renewal.

6.3 No Automatic Renewals

Automatic extension of a *TUE* is not allowed under any circumstances. The physician must re-examine the *Athlete* and determine if his/her medical condition has changed, and if the treatment authorized by the original *TUE* remains appropriate.

7.0 Retroactive *TUEs*

There are situations for which *TUEs* may be granted retroactively.

The evaluation process is identical to the standard *TUE* application procedure: The relevant TUEC studies the application and issues its decision.

Per ISTUE Article 4.3, the following situations may result in a retroactive *TUE*:

- 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 the TUEC to consider, an application for the *TUE* prior to *Sample* collection; or
- c. Applicable rules required the *Athlete* or permitted the *Athlete* to apply for a retroactive *TUE*. This is applicable to *Persons* who are not *International-Level* or *National-Level Athletes* (Code Article 4.4.5) and (where the relevant *NADO* so chooses) to *National-Level Athletes* in sports specified by the relevant *NADO* (ISTUE Article 5.1 Comment); or

[Comment: Such Athletes are strongly advised to have a medical file prepared and ready to demonstrate their satisfaction of the TUE conditions set out at ISTUE Article 4.1, should an application for a retroactive TUE be necessary following Sample collection.]

- d. It is agreed, by *WADA* and by the *ADO* to whom the application for a retroactive *TUE* is or would be made, that fairness requires the grant of a retroactive *TUE*.

7.1 Further Clarification on Retroactive TUEs

- a. A medical emergency or acute medical situation occurs when the *Athlete's* medical condition justifies immediate *Administration of a Prohibited Substance or Method* and failure to treat immediately could significantly put the *Athlete's* health at risk.
 - It is always preferable to address a *TUE* application prospectively rather than retrospectively. *ADOs* granting *TUEs* should have internal procedures to expedite the evaluation and granting of *TUE* for emergency situations, whenever possible, and without putting the athlete's health at risk.
- b. Exceptional circumstances occur when a *TUE* cannot be granted in time through *No Fault* of the *Athlete*. The following examples could be considered "exceptional circumstances":
 - A healthy *Athlete* is suddenly affected by a medical condition days prior to an *Event*, and is unable to request and be granted a *TUE* by a TUEC in the time allotted.
 - A young *Athlete* with a medical condition whose prior *Competition* level did not require an advance *TUE*, and whose anti-doping education is limited, is suddenly named to a national team.

8.0 ADO Authority and TUE Recognition

This section addresses *ADO* authority to grant a *TUE* and when *TUE* decisions are to be recognized and respected by other *ADOs*, as required under *Code* Article 4.4.

The *Code Article* 4.4 Flow Chart in Annex 1 provides a visual representation of the *TUE* recognition process.

8.1 ADO Authority to Grant a TUE

ADO authority to grant a *TUE* is based on the *Athlete's Competition* level.

8.1.1 NADOs

An *Athlete* who is not an *International-Level Athlete* should apply to his/her *NADO* for a *TUE* (*Code Article* 4.4.2).

- When a *NADO* grants a *TUE* to an *Athlete*, it must warn him/her in writing that:
 - a. The *TUE* is valid at the 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 IF or *MEO*, as per *ISTUE Article* 7.1.
- Thereafter, the *NADO* should help the *Athlete* determine when he/she needs to submit the *TUE* to an IF or *MEO* for recognition, guiding and supporting the *Athlete* through the recognition process.
- If the *NADO* denies the *TUE* application, the *Athlete* can appeal exclusively to the national-level appeal body described in *Code Articles* 13.2.2 and 13.2.3 (*Code Article* 4.4.2).

Where national policy requirements and imperatives lead a *NADO* to prioritize certain sports over others in its Test Distribution Plan (*ISTI Article* 4.4.1), the *NADO* may decline to consider advance applications for *TUEs* from *Athletes* in some or all of the non-priority sports.

In such cases, the *NADO* must permit any *Athlete* from whom a *Sample* is subsequently collected to apply for a retroactive *TUE* (*ISTUE Article* 4.3(c)). Any such policy is to be publicized on the *NADO's* Web site for the benefit of affected *Athletes* (*Comment to ISTUE Article* 5.1).

8.1.2 IFs and MEOs

An *International-Level Athlete* applies to his/her IF (*Code Article 4.4.3*).

Athletes may be required by a *MEO* to apply for a *TUE* if the *Athlete* wants to *Use a Prohibited Substance or Method* in connection with the *Event* (*Code Article 4.4.4*).

- The *MEO* ensures a process is available for an *Athlete* to apply for a *TUE* if he/she doesn't already have one.
- A *MEO*-granted *TUE* is effective for the *Event* only (*Code Article 4.4.4.1*).

Per *ISTUE Article 5.6*, each IF and *MEO* must publish a notice in a conspicuous place on its Web site that clearly explains:

1. Which *Athletes* coming under its jurisdiction are required to apply to it for a *TUE*, and when;
2. Which *TUE* decisions of other *ADOs* it will automatically recognize, as per *ISTUE Article 7.1(a)*; and
3. Which *TUE* decisions of other *ADOs* must be submitted to it for recognition, as per *ISTUE Article 7.1(b)*. *WADA* may republish the notice on its Web site.

Using *ADAMS*, IFs are to report a *TUE* grant to *WADA* and to the *Athlete's NADO*.

8.1.3 Change in Athlete's Competition Level

If an *Athlete's Competition* level changes, such that he/she needs a *TUE* from an IF or an *MEO*, rather than apply for a new *TUE*, he/she can ask the IF or *MEO* to recognize his/her pre-existing *TUE* (unless the IF or *MEO* has already stated that it will automatically recognize such *TUEs* without any need to request recognition).

8.2 TUE Recognition

Code Article 4.4 requires *ADOs* to recognize *TUEs* granted by other *ADOs* that satisfy *ISTUE Article 4.1* conditions. However, the appropriate *ADO* may review a granted *TUE* to ensure that the *TUE* has been properly granted, i.e. has truly satisfied *ISTUE* criteria.

- A *TUE* granted by an *Athlete's NADO* that meets *ISTUE* criteria must be recognized by the *Athlete's IF* (*Code Article 4.4.3.1*).
- A *TUE* granted by an *Athlete's NADO* or IF that meets *ISTUE* criteria must be recognized by the *MEO* (*Code Article 4.4.4.2*).

The IF or *MEO* 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 *ADOs*, or those relating to particular *Prohibited*

Substances), provided that such *TUE* decisions have been reported in accordance with ISTI Article 5.4 and therefore are available for review by *WADA*. If the *Athlete's TUE* falls into a category of *TUEs* that are automatically recognized in this way, he/she does not need to take any further action. If not, he/she should submit a request for *TUE* recognition in accordance with ISTUE Article 7.1(b).

To ease the burden on *Athletes*, automatic recognition of *TUE* decisions is strongly encouraged.

If an IF or *MEO* 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 a list of *ADOs* 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 ISTUE Article 5.3, i.e. the notice should be posted on the IF's Web site and sent to *WADA* and to *NADOs*.

To encourage automatic recognition of their *TUE* decisions, *ADOs* should be transparent about the quality and rigour of their *TUE* processes.

9.0 TUE Review and Appeal Processes

The following *Code* Article 4.4 scenarios represent the responsibilities associated with *TUE* review and appeal. (See Guidelines Annex 1 for a visual representation of these processes.)

If: The IF refuses to recognize a *NADO TUE* because it considers the *TUE* doesn't meet ISTUE criteria.

Then: The IF must notify the *Athlete* and his/her *NADO* promptly, with reasons.

The *Athlete* or *NADO* shall have 21 days from such notification to refer the matter to *WADA* for review.

The *NADO*-granted *TUE* 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.

If: The *Athlete* doesn't already have a *NADO*-granted *TUE* for the substance or method in question.

Then: The *Athlete* must apply directly to his/her IF for a *TUE* as soon as the need arises.

If: The IF (or the *NADO*, where it has agreed to consider the application on behalf of the IF) denies the *Athlete's* application.

Then: The IF must notify the *Athlete* promptly, with reasons.

If: The IF grants the *Athlete's* application.

Then: The IF must notify not only the *Athlete*, but also his/her *NADO*.

- If the *NADO* considers that the *TUE* does not meet ISTUE criteria, it has 21 days from such notification to refer the matter to *WADA* for review.
 - If the *NADO* refers the matter to *WADA* for review, the *TUE* granted by the IF remains valid for international-level *Competition* and *Out-of-Competition Testing* (but is not valid for national-level *Competition*) pending *WADA's* decision.
 - If the *NADO* doesn't refer the matter to *WADA* for review, the *TUE* granted by the IF becomes valid for national-level *Competition* as well when the 21-day review deadline expires.
-

Note that if an IF chooses to test an *Athlete* who is not an *International-Level Athlete*, then the IF must recognize a *TUE* granted to that *Athlete* by his/her *NADO*.

If: A *MEO* decides the *TUE* doesn't meet ISTUE criteria and so refuses to recognize or grant the *TUE*

Then: The *MEO* promptly notifies the *Athlete* with reasons.

- A *MEO's* decision not to recognize or grant a *TUE* may be appealed by the *Athlete* to an independent body established or appointed by the *MEO* for that purpose.

- If the *Athlete* doesn't appeal (or the appeal is unsuccessful), he/she may not *Use* the substance or method in question in connection with the *Event*.
- However, any *TUE* granted by the *Athlete's NADO* or IF for that substance or method remains valid outside of that *Event*.

If: A *TUE* decision denying the grant of a *TUE* by an IF (or by *NADO* where it has agreed to consider the application on behalf of an IF) isn't reviewed by *WADA*, or is reviewed by *WADA*, but not reversed upon review.

Then: The decision may be appealed by the *Athlete* and/or the *Athlete's NADO*, exclusively to the Court of Arbitration for Sport (*CAS*).

[Comment to Code 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.]

N.B.: If an *ADO* refuses to recognize a *TUE* granted by another *ADO* only because medical records or other information are missing that are needed to demonstrate satisfaction with *ISTUE* criteria, then the matter shouldn't be referred to *WADA*. Instead, the file should be completed and re-submitted to the appropriate *ADO*.

10.0 ADO TUEC Responsibilities

ADOs must establish a process to review *TUEs*. They may have a permanent TUEC or rapidly set up TUECs for each individual case, depending on the expertise and availability of the experts in their network.

While a *MEO* 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 *MEO* whether it sets up its own TUEC for this purpose, or outsources the task by agreement to a Third Party (such as SportAccord). 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 (ISTUE Article 5.2).

The TUEC promptly evaluates the *TUE* application and issues its decision, which is considered the *ADO's* final decision. The TUEC may seek whatever medical or scientific expertise it deems appropriate in reviewing any application for a *TUE*.

Each *NADO*, *IF* and *MEO* has the following TUEC-related responsibilities:

- **Set up a network of physicians** responsible for evaluating *TUE* applications. TUECs should include at least three physicians with experience in the care and treatment of *Athletes* and a sound knowledge of clinical, sports and exercise medicine (ISTUE Article 5.2). One of the member physicians acts as TUEC chair.

For applications involving *Athletes* with impairments, at least one TUEC member must possess general experience in the care and treatment of *Athletes* with impairments, or possess specific experience in relation to the *Athlete's* particular impairments(s) (ISTUE Article 5.2(a)).

- **Establish a clear process for applying to its TUEC for a *TUE*** that complies with ISTUE requirements. The TUEC must also publish details of the application process on its Web site and send the information to *WADA* to potentially post on its Web site (ISTUE Article 5.3).
- **Promptly report (in English or French) all decisions of its TUEC** to grant or deny *TUEs*, and all decisions to recognize or refuse to recognize other *ADOs'* *TUE* decisions, through *ADAMS* or any other system approved by *WADA*. In respect of *TUEs* granted, the information reported shall include (in English or French):
 - a. Not only the approved substance or method, but also the dosage(s), frequency and route of *Administration* permitted, the duration of the *TUE*, and any conditions imposed in connection with the *TUE*; (ISTUE 5.4(a)) and
 - b. The *TUE* application form and a summary of the relevant clinical information (translated into English or French) establishing that ISTUE Article 4.1 conditions have been satisfied, accessible only by *WADA*, the *Athlete's* *NADO* and *IF*, and the *MEO* organizing an *Event* in which the *Athlete* wishes to compete (ISTUE 5.4(b)).

The process of *TUE* recognition is greatly facilitated by the use of *ADAMS*.

10.1.1 Conflict of Interest and Confidentiality

To ensure a level of independence of decisions, TUEC members should have no political responsibility in the *ADO* that appoints them, and all must sign a conflict of interest and confidentiality declaration (ISTUE Article 5.2(b)). The TUEC Confidentiality Declaration template available on *WADA's* Web site is provided in Guidelines Annex 2.

Any TUEC member having a conflict of interest with their *NADO* or IF should be excluded from the examination of *TUE* applications made by *Athletes* who are members of their *NADO* or IF.

10.2 21-Day Deadline for Decisions

The TUEC decides as soon as possible whether or not to grant the *TUE* application, usually (i.e. unless exceptional circumstances apply) within no more than 21 days of receipt of a complete application. Where a *TUE* application 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* (ISTUE Article 6.7).

The TUEC's decision is to be communicated in writing to the *Athlete* and made available to *WADA* and to other *ADOs* via *ADAMS* or any other system approved by *WADA*, in accordance with ISTUE Article 5.4 (ISTUE Article 6.8).

- 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 TUEC is permitting, reflecting the clinical circumstances, and 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.

10.2.1 Failure to Meet Deadline

An *Athlete* who has not received a response to his/her *TUE* application after the 21-day period or before the *Event* is to contact the *ADO* to confirm the status of his/her *TUE* application.

The *ADO* is obligated to render a decision within a reasonable period of time on a *TUE* application submitted in due form. If this obligation isn't fulfilled, the *Athlete* may seek a *TUE* review by *WADA*. Absence of a decision may be considered a denial of the application for the purposes of rights of appeal provided for in *Code* Article 4.4.9.

11.0 WADA TUE Monitoring and Review

Under *Code* Article 4.4.6, WADA must review an IF's decision:

- not to recognize a *TUE* granted by the *NADO*, when requested by the *Athlete* or the *Athlete's NADO*.

The IF must give reasons why it will not recognize the *TUE*. WADA may refer the decision back to the IF if the refusal is due to missing information (ISTUE Article 8.4).

- to grant a *TUE*, when requested by the *Athlete's NADO*.

The *NADO* must give reasons why it believes that ISTUE criteria are not satisfied.

WADA may review any *TUE* decisions at any time, whether upon request by those affected or on its own initiative.

If a *TUE* decision under review meets ISTUE criteria, WADA won't interfere with it. If ISTUE criteria aren't met, WADA will reverse it.

These reviews are carried out by the WADA TUEC created in compliance with the requirements outlined in ISTUE Article 5.2.

11.1 WADA TUE Review

The *TUE* review process begins with a request to WADA. (For a visual representation of the *TUE* review process, see Guidelines Annex 1: *Code* Article 4.4 Flow Chart.)

The process of requesting WADA to review a *TUE* is identical for *Athletes* and *ADOs*:

1. *TUE* review requests must be submitted to WADA in writing by registered mail, accompanied by payment of the application fee and copies of all of the information specified in ISTUE Article 6.2, or (in the review of a *TUE* denial or of a decision not to recognize a *NADO-granted TUE*) all of the information that the *Athlete* submitted in connection with the original *TUE* application (ISTUE Article 8.2).
2. The documents provided to WADA are to contain all of the information sent during the initial submission (complete file), along with the initial decision issued and the explanation provided by the *ADO* on why the *TUE* was not granted or not recognized.
3. The request must be copied to the party whose decision would be the subject of the review, and to the *Athlete*, if he/she is not requesting the review.

4. The certificate of payment of the required application fee must be included once *WADA* agrees to review the case. This fee is non-refundable, regardless of the outcome of the review. *WADA* provides all of the bank information concerning fee payment upon request.
5. The review procedure commences upon *WADA*'s receipt of payment and all necessary documentation.
6. Upon receipt of the complete request for review, *WADA* sets up and coordinates the WADA TUEC, which will review the case and issue its decision, generally within 21 days. *WADA* will then inform all of the relevant parties of the decision issued.
7. Although *WADA* has the right to request further information, the WADA TUEC generally reviews the original *TUE* decision based on the original file submitted. If additional medical information is to be considered, the *TUE* application should be re-submitted to the *Athlete's IF/NADO*.

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 refer the *TUE* decision to the WADA TUEC for review. If *WADA* decides not to refer the *TUE* decision, it will return the application fee to the *Athlete*.

Any decision by *WADA* not to refer the *TUE* decision to the WADA TUEC is final and may not be appealed. However, the original *TUE* decision may still be appealable, as set out in *Code* Article 4.4.7 (ISTUE Article 8.3).

Where the request is for review of a *TUE* decision of that *WADA* is obliged to review, *WADA* may refer the decision back to the IF or *NADO*, as applicable (ISTUE Article 8.4):

- a. for clarification, e.g. if the reasons are not clearly set out in the decision; and/or
- b. for re-consideration, e.g. if the *TUE* was only denied because medical tests or other information required to demonstrate satisfaction of the ISTUE Article 4.1 conditions were missing.

The WADA TUEC may review the case based only on the originally submitted information but may seek additional information from the *ADO* and/or the *Athlete*, including further studies as described in ISTUE Article 6.5. The WADA TUEC may obtain the assistance of other medical or scientific experts as it deems appropriate (ISTUE Article 8.5).

Where the WADA TUEC reviews a decision of an IF that has been referred to it pursuant to *Code* Article 4.4.3 (i.e. a mandatory review), it may require whichever *ADO* “loses” the review (i.e. the *ADO* whose view it does not uphold) to:

- a. Reimburse the application fee to the party that referred the decision to *WADA* (if applicable); and/or
- b. Pay the costs incurred by *WADA* in respect of that review, to the extent they are not covered by the application fee (ISTUE Article 8).

The WADA TUEC shall reverse any denial of a *TUE* where the *TUE* application met the ISTUE Article 4.1 conditions, i.e. it shall grant the *TUE* (ISTUE Article 8.7).

Where the WADA TUEC reverses a *TUE* decision that *WADA* reviewed under its own discretion, *WADA* may require the *ADO* that made the initial decision to pay the costs incurred by *WADA* in respect of that review (ISTUE Article 8.9).

WADA shall communicate the reasoned decision of the WADA TUEC promptly to the *Athlete* and to his/her *NADO*, IF, and (if applicable) the *MEO* (ISTUE Article 8.10).

11.2 TUE Status During WADA Review

The review procedure does not suspend the initial decision, which remains in effect throughout the duration of the review until the WADA TUEC issues its decision. However, if the *Athlete* had been granted a *TUE* by a *NADO* that was not recognized by an IF, then the *TUE* would only be valid at a national-level *Competition* (and for *Out-of-Competition Testing*), pending *WADA*’s review, but not for international-level *Competition* (*Code* Article 4.4.3).

If the *TUE* was granted by an IF and referred to *WADA* for review by a *NADO*, the *TUE* is valid for international-level *Competition* and *Out-of-Competition Testing*, but not valid for national-level *Competition*, pending *WADA*’s review.

If the WADA TUEC overturns the initial decision and grants the *TUE*, the *Athlete* may start to *Use* the substance or method according to the *TUE* granted by the WADA TUEC. The *TUE* will be valid at both national and international-level *Competition*. Conversely, a *TUE* refused by *WADA* will not be valid at either level of *Competition*.

The *ADO* that issued the initial decision has the right to appeal before the *CAS*. (See Guidelines Section 11.3 below.) Unless the *CAS* orders otherwise, *WADA*’s decision remains in effect until the *CAS* hands down the final decision.

11.3 Appeal of WADA Decisions

As per *Code* Article 13.4:

If the **initial decision is overturned** by the WADA TUEC, only the *Athlete* or the *ADO* whose decision was invalidated may appeal this decision before the *CAS*.

If the **initial decision denying a TUE isn't invalidated** by the WADA TUEC, the decision may be appealed:

- Before the *CAS* by *International-Level Athletes*, or
- Before the national-level review body by other *Athletes*. If the national-level review body invalidates the decision to deny the *TUE*, *WADA* may appeal such decision before the *CAS*.

12.0 TUE Management Within ADAMS

ADAMS is a Web-based system designed in strict compliance with the *Code* to assist stakeholders and *WADA* in their anti-doping operations.

As a central clearinghouse for *Doping Control Testing* data and results management decisions, *ADAMS* allows for data entry, reporting, sharing, and storage in a highly secure environment, with access restricted to relevant authorized parties.

The *ADAMS TUE* management module provides the following services:

- Online submission of *TUE* applications by
 - *Athletes*;
 - *Athlete* physicians; and
 - *ADOs* to TUEC physicians.
- Online management of *TUE* applications
- Notification of receipt to *Athletes*
- Notification of refusal to grant a *TUE* to *Athletes*
- Dispatch of *TUE* certificates to *Athletes*
- Online notification of the expiry/change in status of a *TUE* to relevant parties
- Sharing of information relating to the *TUE* with all relevant parties
- Recognition by IF of *TUE* granted by *NADOs*
- Link between *TUEs* and *AAFs*
- Search function and printing of reports.

12.1 ADAMS and Athletes

ADAMS enables *Athletes* to complete forms and submit their *TUE* applications online, receive online notification from *ADOs*, and consult changes in the status of their applications.

12.2 ADAMS and Physicians

Athlete physicians can complete *TUE* application forms online after identifying themselves to the *Athlete's ADO*.

12.3 ADAMS and ADOs

ADAMS enables *ADOs* to manage *TUE* applications online. *ADOs* can grant/deny *TUEs*, send notification to *Athletes* and confirm whether a *TUE* is under review by *WADA*.

ADOs can also use *ADAMS* to recognize *TUEs* granted by another *ADO*.

13.0 Definitions

13.1 2015 Code Defined Terms

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 (AAF): 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 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 (ADO): 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*, WADA, International Federations, and *National Anti-Doping Organizations*.

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 authority 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, 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: This definition makes it clear that 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, to expand 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 in fitness 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.]

Athlete Support Personnel: Any coach, trainer, manager, agent, team staff, official, medical, paramedical personnel, parent or any other *Person* working with, treating or assisting an *Athlete* participating in or preparing for sports *Competition*.

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*.

Atypical Finding: A report from a WADA-accredited laboratory or other WADA-approved laboratory which requires further investigation as provided by the International Standard for Laboratories or related Technical Documents prior to the determination of an *Adverse Analytical Finding*.

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 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.

Doping Control: All steps and processes from test distribution planning through to ultimate disposition of any appeal including all steps and processes in between such as provision of whereabouts information, *Sample* collection and handling, laboratory analysis, *TUEs*, results management and hearings.

Event: A series of individual *Competitions* conducted together under one ruling body (e.g., the Olympic Games, FINA World Championships, 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 period commencing twelve hours 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*.

[Comment to In-Competition: An International Federation or ruling body for an Event may establish an "In-Competition" period that is different than the Event Period.]

International Event: An *Event* or *Competition* where the International Olympic Committee, the International Paralympic Committee, an International Federation, a *Major Event Organization*, or another international sport organization is the ruling body for 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 (IS): 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 (MEOs): The continental associations of *National Olympic Committees* and other international multisport organizations that function as the ruling body for any continental, regional or other *International Event*.

Marker: A compound, group of compounds or biological variable(s) that indicates the *Use of a Prohibited Substance or Prohibited Method*.

Metabolite: Any substance produced by a biotransformation process.

Minor: A natural *Person* who has not reached the age of eighteen years.

National Anti-Doping Organization (NADO): 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 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*.

No Fault or Negligence: The *Athlete* or other *Person's* establishing that he or she did not know or suspect, and could not reasonably have known or suspected even with the exercise of utmost caution, that he or she had *Used* or been administered the *Prohibited Substance or Prohibited Method* or otherwise violated an anti-doping rule. Except in the case of a *Minor*, for any violation of Article 2.1, the *Athlete* must also establish how the *Prohibited Substance* entered his or her system.

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

Person: A natural *Person* or an organization or other entity.

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, 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 steroids and intended to have control over the steroids. Similarly, in the example of 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 steroids. 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*.

Registered Testing Pool (RTP): The pool of highest-priority *Athletes* established separately at the international level by International Federations and at the national level by *National Anti-Doping Organizations*, who are subject to focused *In-Competition* and *Out-of-Competition Testing* as part of that International Federation's or *National Anti-Doping Organization's* test distribution plan and therefore are required to provide whereabouts information as provided in Article 5.6 and the International Standard for Testing and Investigations.

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.]

Signatories: Those entities signing the *Code* and agreeing to comply with the *Code*, as provided in Article 23.

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

TUE: Therapeutic Use Exemption, as described in Article 4.4.

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.

13.2 ISTUE Defined Terms

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 (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*.

13.3 ISTI Defined Terms

Results Management Authority (RMA): The organization that is responsible, in accordance with *Code* Article 7.1, for the management of the results of *Testing* (or other evidence of a potential anti-doping rule violation) and hearings, whether (1) an *Anti-Doping Organization* (for example, the International Olympic Committee or other *Major Event Organization*, *WADA*, an International Federation, or a *National Anti-Doping Organization*); or (2) another organization acting pursuant to the authority of and in accordance with the rules of the *Anti-Doping Organization* (for example, a National Federation that is a member of an International Federation). In respect of Whereabouts Failures, the Results Management Authority shall be as set out in Article I.5.1.

Test Distribution Plan: A document written by an *Anti-Doping Organization* that plans *Testing* on *Athletes* over whom it has Testing Authority, in accordance with the requirements of Article 4 of the International Standard for Testing and Investigations.

Testing Authority: The organization that has authorized a particular *Sample* collection, whether (1) an *Anti-Doping Organization* (for example, the International Olympic Committee or other *Major Event Organization*, *WADA*, an International Federation, or a *National Anti-Doping Organization*); or (2) another organization conducting *Testing* pursuant to the authority of and in accordance with the rules of

the *Anti-Doping Organization* (for example, a National Federation that is a member of an International Federation).

13.4 ISL Defined Terms

Laboratory(ies): (A) WADA-accredited laboratory(ies) applying test methods and processes to provide evidentiary data for the detection of *Prohibited Substances, Methods* or *Markers* on the *Prohibited List* and, if applicable, quantification of a Threshold Substance in *Samples* of urine and other biological matrices in the context of anti-doping activities.

Major Event: A series of individual international *Competitions* conducted together under an international multi-sport organization functioning as a ruling body (e.g., the Olympic Games, Pan American Games) and for which a significant increase of resources and capacity, as determined by WADA, is required to conduct *Doping Control* for the *Event*.

13.5 ISPPPI Defined Terms

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

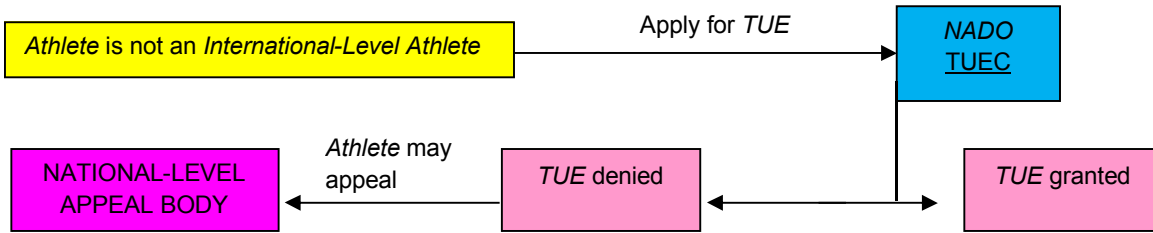
[3.2 Comment: It is understood that Personal Information includes, but is not limited to, information relating to an *Athlete's* name, date of birth, contact details and sporting affiliations, whereabouts, designated therapeutic use exemptions (if any), anti-doping test results, and results management (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 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, retaining, storing, disclosing, transferring, transmitting, amending, deleting or otherwise making use of Personal Information.

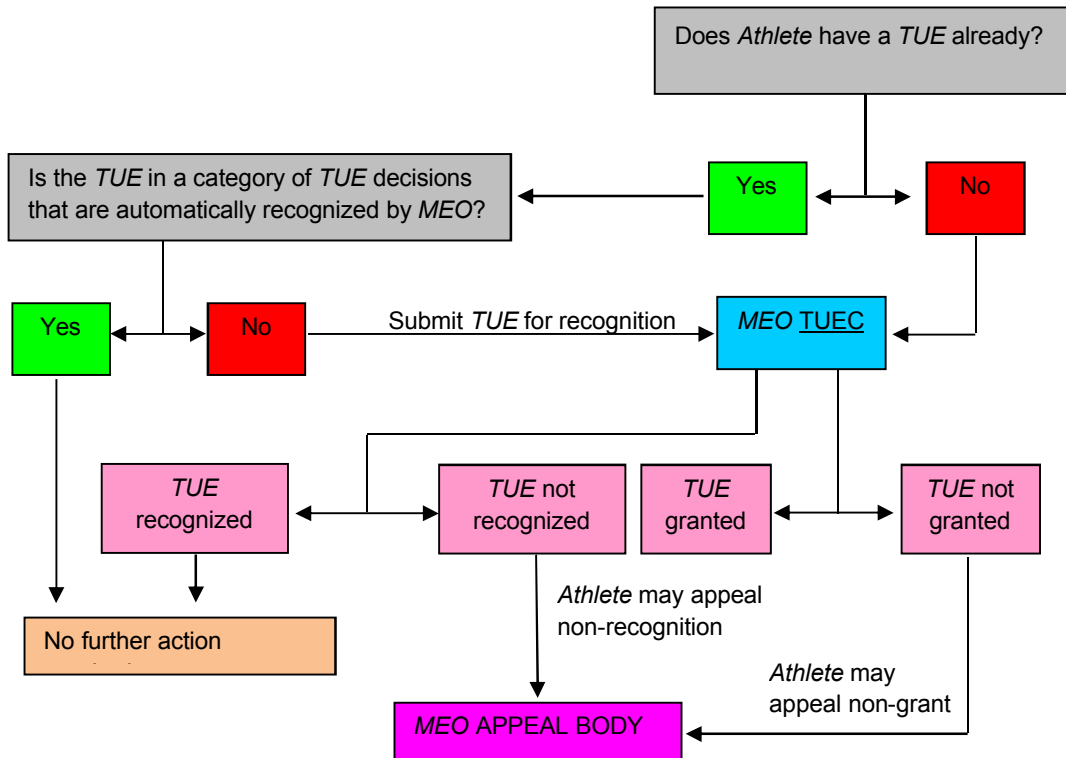
Third Party: Any natural *Person* or legal entity other than the natural *Person* to whom the relevant Personal Information relates, *Anti-Doping Organizations* and Third-Party Agents.

Annex 1: Code Article 4.4 Flow Chart

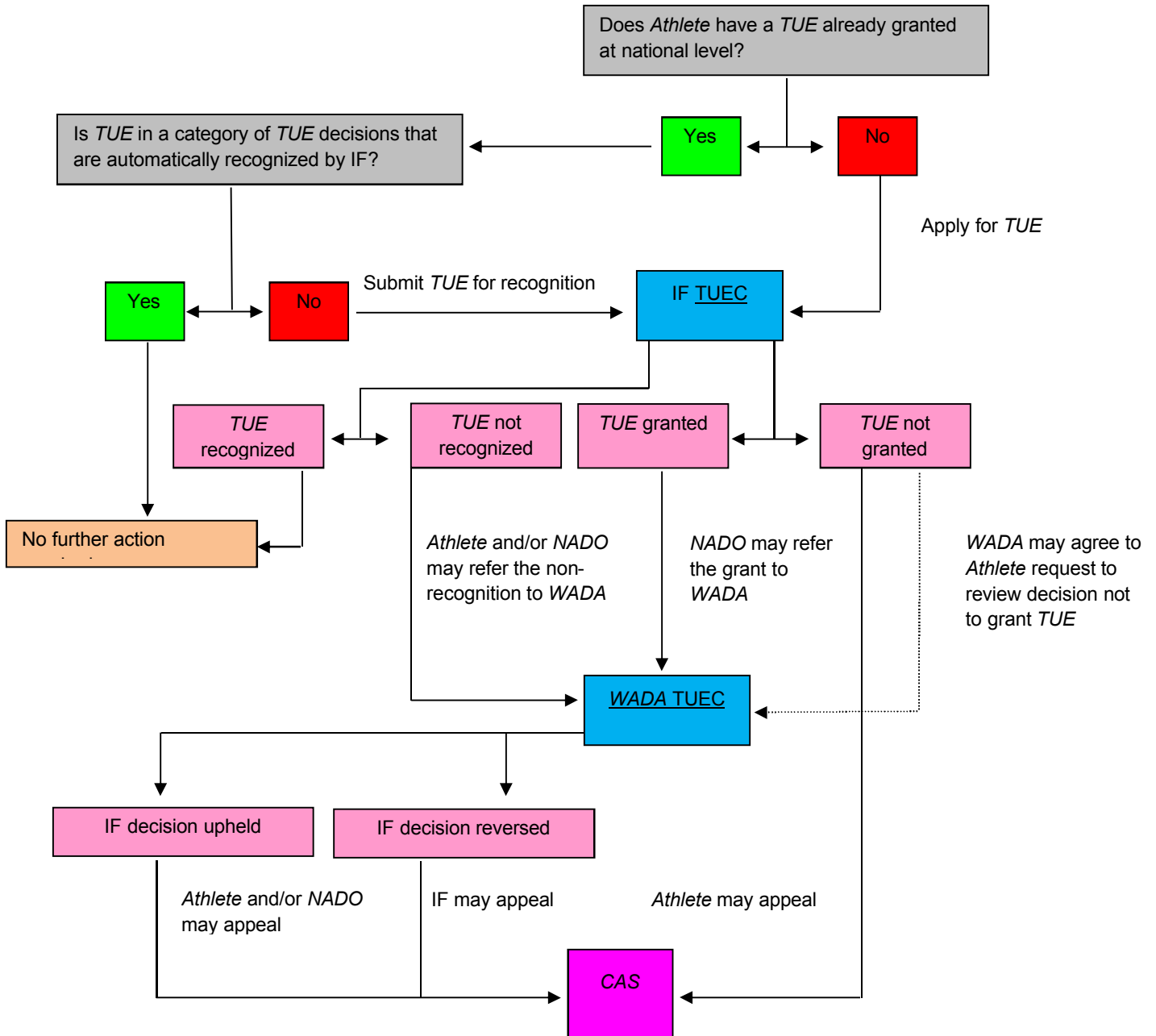
TUE procedure if Athlete is not an International-Level Athlete when need for TUE arises.



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



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



Annex 2: Confidentiality Template

CONFLICT OF INTEREST AND CONFIDENTIALITY DECLARATION

As a member of the Therapeutic Use Exemption Committee (TUEC) of [Your organization name], I, the undersigned, _____, affirm and acknowledge that, by signing this declaration, I am bound by the terms of such declaration.

I understand that the nature of my participation as a member of the aforementioned TUEC is such that I shall come into contact with or be made aware of sensitive and confidential information.

I swear or solemnly state that, as a member of the TUEC of [Your organization name], I shall respect all of the requirements relating to the confidentiality of the information that I receive or that is brought to my attention in any way whatsoever during the course of my duties and functions throughout and beyond the duration of my participation.

With the exception of legal obligations, authorization by virtue of my office, or the express authorization of [*Person* in charge of your organization], I shall not reveal or hand over to anybody, particularly to representatives of the media, any confidential information or document that is brought to my attention or is in my possession, either directly or indirectly through my participation as a member of the TUEC of [Your organization name], excluding information that has already been made public or is in my possession independently of [Your organization name]. I shall not use my title as member of the TUEC for any public declaration.

I, the undersigned, acknowledge that [Your organization name] holds all of the property rights and titles to all of the material, copies, extracts, summaries and other confidential information drawn up during my participation as a member of the TUEC of [Your organization name].

Furthermore, I understand that the violation of my confidentiality obligation may result in possible legal proceedings against me and the immediate termination of my participation as a member of the TUEC of [Your organization name].

In the *event* of any conflict of interest with a party to the application for a Therapeutic Use Exemption that the TUEC of [Your organization name] may have to handle, I shall immediately inform [*Person* in charge of your organization] and abstain from taking part in the decision procedure for the specific case in question.

DATED THE _____ DAY OF _____, 20_____

BY _____

(SIGNATURE)