

WORLD ANTI-DOPING CODE

INTERNATIONAL STANDARD-
~~FOR~~

THERAPEUTIC USE EXEMPTIONS

~~January 2011~~

JANUARY 2015



International Standard for Therapeutic Use Exemptions

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

~~The~~ International Standard for Therapeutic Use Exemptions was first adopted in 2004 and ~~became effective in 2005. The enclosed represents version 5.0 that~~ came into effect 1 January 2005. Further revisions were made in 2009, 2010 and 2011. The enclosed ISTUE incorporates revisions to the ~~International Standard for Therapeutic Use Exemptions that were~~ ISTUE and was approved ~~by~~ at the World ~~Anti-Conference on Doping Agency in Sport in Johannesburg~~ by the WADA Executive Committee on ~~18 September 2010. The revised International Standard for Therapeutic Use Exemptions is effective as of 1 January 2011.~~

~~Published on 1 October 2010 by:–~~

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~~**PREAMBLE** The World Anti-Doping Code International Standard for Therapeutic Use Exemptions (TUE) is a Level 2 mandatory International Standard developed as part of the World Anti-Doping Program. 15 November 2013. It will come into effect on 1 January 2015.~~

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

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~~The International Standard for TUE (version 5.0) will come into effect on 1 January 2011.~~

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PART ONE: INTRODUCTION, CODE 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 ~~ensure that the process of granting therapeutic use exemptions is harmonized across sports and countries.~~ 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.

~~The Code permits Athletes to apply for therapeutic use exemptions (TUE) i.e. permission to use, for therapeutic purposes, substances or methods contained in the List of Prohibited Substances or Methods where Use would otherwise be prohibited.~~

~~The International Standard for TUE includes criteria for granting a TUE, confidentiality of information, the formation of Therapeutic Use Exemptions Committees and the TUE application process.~~

~~This Standard applies to all Athletes as defined by and subject to the Code i.e. able-bodied Athletes and Athletes with disabilities.~~

~~[Comment: This Standard will be applied according to an individual's circumstances. For example, an exemption that is appropriate for an Athlete with a disability may be inappropriate for other Athletes.]~~

~~The World Anti-Doping Program encompasses all of the elements needed in order to ensure optimal harmonization and best practice in international and national anti-doping programs. The main elements are: the Code (Level 1), International Standards (Level 2), and Models of Best Practice (Level 3).~~

~~In the introduction to the Code, the purpose and implementation of the International Standards are summarized as follows:~~

~~“International Standards for different technical and operational areas within the anti-doping program will be developed in consultation with the Signatories and governments and approved by WADA. The purpose of the International Standards is harmonization among Anti-Doping Organizations responsible for specific technical and operational parts of the anti-doping programs. Adherence to the International Standards is mandatory for compliance with the Code. The International Standards may be revised from time to time by the WADA Executive Committee after reasonable consultation with the Signatories and governments. Unless provided otherwise in the Code, International Standards and all revisions shall become effective on the date specified in the International Standard or revision.”~~

~~Compliance with an International Standard (as opposed to another alternative standard, practice or procedure) shall be sufficient to conclude that the procedures covered by the Terms used in this International Standard were performed properly. Definitions specified in that are defined terms from the Code are written in italics. Additional definitions specific to the Terms that are defined in this International Standard for TUE are underlined.~~

2.0 ~~2.0~~ Code Provisions

The following articles in the ~~2009~~2015 Code are directly relevant to the International Standard for ~~TUE~~Therapeutic Use Exemptions:

~~Code Article 4.4 — Therapeutic Use~~ Code Article 4.4 Therapeutic Use Exemptions ("TUEs").

~~WADA has adopted an International Standard for the process of granting therapeutic use exemptions.~~

~~Each International Federation shall ensure, for International Level Athletes or any other Athlete who is entered in an International Event, that a process is in place whereby Athletes with documented medical conditions requiring the Use of a Prohibited Substance or a Prohibited Method may request a therapeutic use exemption. Athletes who have been identified as included in their International Federation's Registered Testing Pool may only obtain therapeutic use exemptions in accordance with the rules of their International Federation. Each International Federation shall publish a list of those International Events for which a therapeutic use exemption from the International Federation is required. Each National Anti-Doping Organization shall ensure, for all Athletes within its jurisdiction that have not been included in an International Federation Registered Testing Pool, that a process is in place whereby Athletes with documented medical conditions requiring the Use of a Prohibited Substance or a Prohibited Method may request a therapeutic use exemption. Such requests shall be evaluated in accordance with the International Standard for Therapeutic~~

~~Use Exemptions. International Federations and National Anti-Doping Organizations shall promptly report to WADA through ADAMS the granting of any therapeutic use exemption except as regards national-level Athletes who are not included in the National Anti-Doping Organization's Registered Testing Pool.~~

~~WADA, on its own initiative, may review at any time the granting of a therapeutic use exemption to any International-Level Athlete or national-level Athlete who is included in his or her National Anti-Doping Organization's Registered Testing Pool. Further, upon the request of any such Athlete who has been denied a therapeutic use exemption, WADA may review such denial. If WADA determines that such granting or denial of a therapeutic use exemption did not comply with the International Standard for Therapeutic Use Exemptions, WADA may reverse the decision.~~

~~If, contrary to the requirement of this Article, an International Federation does not have a process in place where Athletes may request therapeutic use exemptions, an International-Level Athlete may request WADA to review the application as if it had been denied.~~

4.4.1 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 if it is consistent with the provisions of a TUE granted in accordance with the International Standard for Therapeutic Use Exemptions.

4.4.2 An Athlete who is not an International-Level Athlete should apply to his or her National Anti-Doping Organization for a TUE. If the National Anti-Doping Organization denies the application, the Athlete may appeal exclusively to the national-level appeal body described in Articles 13.2.2 and 13.2.3.

4.4.3 An Athlete who is an International-Level Athlete should apply to his or her International Federation.

4.4.3.1 Where the Athlete already has a TUE granted by his or her National Anti-Doping Organization for the substance or method in question, if that TUE meets the criteria set out in the International Standard for Therapeutic Use Exemptions, then the International Federation must recognize it. If the International Federation considers that the TUE does not meet those criteria and so refuses to recognize it, it must notify the Athlete and his or her National Anti-Doping Organization promptly, with reasons. The Athlete or the National Anti-Doping Organization shall have 21 days from such notification to refer the matter to WADA for review. If the matter is

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

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

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

If an International Federation chooses to test an Athlete who is not an International-Level Athlete, it must recognize a TUE granted to that Athlete by his or her National Anti-Doping Organization.]

~~Presence of a Prohibited Substance or its Metabolites or Markers (Article 2.1), Use or Attempted Use of a Prohibited Substance or a Prohibited Method (Article 2.2), Possession of Prohibited Substances and Prohibited Methods (Article 2.6) or Administration or Attempted Administration of a Prohibited Substance or Prohibited Method (Article 2.8) consistent with the~~

~~provisions of an applicable therapeutic use exemption issued pursuant to the *International Standard for Therapeutic Use Exemptions* shall not be considered an anti-doping rule violation.~~ 4.4.4 A Major Event Organization may require Athletes to apply to it for a TUE if they wish to Use a Prohibited Substance or a Prohibited Method in connection with the Event. In that case:

~~Code Article 13.4 — Appeals from Decisions Granting or Denying a Therapeutic Use Exemption—~~

4.4.4.1 The Major Event Organization must ensure a process is available for an Athlete to apply for a TUE if he or she does not already have one. If the TUE is granted, it is effective for its Event only.

4.4.4.2 Where the Athlete already has a TUE granted by his or her National Anti-Doping Organization or International Federation, if that TUE meets the criteria set out in the International Standard for Therapeutic Use Exemptions, the Major Event Organization must recognize it. If the Major Event Organization decides the TUE does not meet those criteria and so refuses to recognize it, it must notify the Athlete promptly, explaining its reasons.

4.4.4.3 A decision by a Major Event Organization not to recognize or not to grant a TUE may be appealed by the Athlete exclusively to an independent body established or appointed by the Major Event Organization for that purpose. If the Athlete does not appeal (or the appeal is unsuccessful), he or she may not Use the substance or method in question in connection with the Event, but any TUE granted by his or her National Anti-Doping Organization or International Federation for that substance or method remains valid outside of that Event.

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

4.4.5 If an Anti-Doping Organization chooses to collect a Sample from a Person who is not an International-Level or National-Level Athlete, and that Person is Using a Prohibited Substance or Prohibited Method for therapeutic reasons, the Anti-Doping Organization may permit him or her to apply for a retroactive TUE.

4.4.6 WADA must review an International Federation's decision not to recognize a TUE granted by the National Anti-Doping Organization that is

referred to it by the Athlete or the Athlete's National Anti-Doping Organization. In addition, WADA must review an International Federation's decision to grant a TUE that is referred to it by the Athlete's National Anti-Doping Organization. WADA may review any other TUE decisions at any time, whether upon request by those affected or on its own initiative. If the TUE decision being reviewed meets the criteria set out in the International Standard for Therapeutic Use Exemptions, WADA will not interfere with it. If the TUE decision does not meet those criteria, WADA will reverse it.

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

4.4.7 Any TUE decision by an International Federation (or by a National Anti-Doping Organization where it has agreed to consider the application on behalf of an International Federation) that is not reviewed by WADA, or that is reviewed by WADA but is not reversed upon review, may be appealed by the Athlete and/or the Athlete's National Anti-Doping Organization, exclusively to CAS.

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

4.4.8 A decision by WADA to reverse a TUE decision may be appealed by the Athlete, the National Anti-Doping Organization and/or the International Federation affected, exclusively to CAS.

4.4.9 A failure to take action within a reasonable time on a properly submitted application for grant/recognition of a TUE or for review of a TUE decision shall be considered a denial of the application.

~~Decisions by WADA reversing the grant or denial of a therapeutic use exemption~~

Code Article 13.4 Appeals relating to TUEs

~~TUE decisions may be appealed exclusively to CAS by the Athlete or the Anti-Doping Organization whose decision was reversed. Decisions by Anti-Doping Organizations other than WADA denying therapeutic use exemptions, which are not reversed by WADA, may be appealed by~~

~~International Level Athletes to CAS and by other Athletes to the national level reviewing body described in Article 13.2.2. If the national level reviewing body reverses the decision to deny a therapeutic use exemption, that decision may be appealed to CAS by WADA.~~

~~When an Anti-Doping Organization fails to take action on a properly submitted therapeutic use exemption application within a reasonable time, the Anti-Doping Organization's failure to decide may be considered a denial for purposes of the appeal rights provided in this Article.~~

~~Code Article 14.5 — Doping Control Information Clearinghouse~~ [as provided in Article 4.4.](#)

~~WADA shall act as a central clearinghouse for Doping Control Testing data and results for International Level Athletes and national level Athletes who have been included in their National Anti-Doping Organization's Registered Testing Pool. To facilitate coordinated test distribution planning and to avoid unnecessary duplication in Testing by the various Anti-Doping Organizations, each Anti-Doping Organization shall report all In-Competition and Out-of-Competition tests on such Athletes to the WADA clearinghouse as soon as possible after such tests have been conducted. This information will be made accessible to the Athlete, the Athlete's National Federation, National Olympic Committee or National Paralympic Committee, National Anti-Doping Organization, International Federation, and the International Olympic Committee or International Paralympic Committee.~~

~~To enable it to serve as a clearinghouse for Doping Control Testing data, WADA has developed a database management tool, ADAMS, that reflects emerging data privacy principles. In particular, WADA has developed ADAMS to be consistent with data privacy statutes and norms applicable to WADA and other organizations using ADAMS.~~

~~Private information regarding an Athlete, Athlete Support Personnel, or others involved in anti-doping activities shall be maintained by WADA, which is supervised by Canadian privacy authorities, in strict confidence and in accordance with the International Standard for the protection of privacy. WADA shall, at least annually, publish statistical reports summarizing the information that it receives, ensuring at all times that the privacy of Athletes is fully respected and make itself available for discussions with national and regional data privacy authorities.~~

~~Code Article 15.4 — Mutual Recognition~~

~~15.4.1 Subject to the right to appeal provided in Article 13, Testing, therapeutic use exemptions and hearing results or other final adjudications of any Signatory which are consistent with the Code and are within that Signatory's authority, shall be recognized and respected by all other Signatories.~~

~~[Comment to Article 15.4.1: There has in the past been some confusion in the interpretation of this Article with regard to therapeutic use exemptions. Unless provided otherwise by the rules of an International Federation or an agreement with an International Federation, National Anti-Doping Organizations do not have "authority" to grant therapeutic use exemptions to International Level Athletes.]~~

~~15.4.2 Signatories shall recognize the same actions of other bodies which have not accepted the Code if the rules of those bodies are otherwise consistent with the Code.~~

~~[Comment to Article 15.4.2: Where the decision of a body that has not accepted the Code is in some respects Code compliant and in other respects not Code compliant, Signatories should attempt to apply the decision in harmony with the principles of the Code. For example, if in a process consistent with the Code a non-Signatory has found an Athlete to have committed an anti-doping rule violation on account of the presence of a Prohibited Substance in his body but the period of Ineligibility applied is shorter than the period provided for in the Code, then all Signatories should recognize the finding of an anti-doping rule violation and the Athlete's National Anti-Doping Organization should conduct a hearing consistent with Article 8 to determine whether the longer period of Ineligibility provided in the Code should be imposed.]~~

3.0 ~~Terms and~~ Definitions and Interpretation

3.1 Defined ~~Terms from the Code~~ terms from the 2015 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 entitylaboratory 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: 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 participatescompetes in sport at the international level (as defined by each International Federation), or the national level (as defined by each *National Anti-Doping Organization*, ~~including but not limited to those Persons in its Registered Testing Pool~~), and any other competitor in sport who is otherwise subject to the jurisdiction of any *Signatory* or other sports organization accepting the *Code*. ~~All provisions of the Code, including, for example, Testing and therapeutic use exemptions, shall be applied to international and national level competitors. Some National Anti-Doping Organizations may elect to test and~~. An Anti-Doping Organization has discretion to apply anti-doping rules to ~~recreational level or masters competitors who are not current or potential national caliber competitors. National Anti-Doping Organizations are not required, however, to apply all aspects of the Code to such Persons. Specific national rules may be established for Doping Control for non-international level or non-national level competitors without being in conflict with the Code. Thus, a country could elect to test recreational level competitors but not require therapeutic use exemptions or whereabouts information. In the same manner, a Major Event Organization holding an Event only for masters level competitors could elect to test the competitors but not require advance therapeutic use exemptions or whereabouts information~~ 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 ~~(Administration or Attempted Administration)~~ 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: This definition makes it clear that all ~~international~~International- and ~~national-caliber~~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. ~~At the national level, anti-doping rules adopted pursuant to the Code shall apply, at a minimum, to all persons on national teams and all persons qualified to compete in any national championship in any sport. That does not mean, however, that all such Athletes shall be included in a National Anti-Doping Organization's Registered Testing Pool.~~ The definition also allows each National Anti-Doping Organization, if it chooses to do so, to expand its anti-doping program beyond ~~national-caliber~~International- or National-Level Athletes to competitors at lower levels of ~~competition~~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~~Competition should receive the benefit of anti-doping information and education.]

Code: The World Anti-Doping Code.

Competition: A single race, match, game or singular ~~athletic~~sport contest. For example, a basketball game or the finals of the Olympic 100-meter race in athletics. For stage races and other ~~athletic~~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, therapeutic use exemptions, 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).

~~**Event Period:** The time between the beginning and end of an *Event*, as established by the ruling body of the *Event*.~~

In-Competition: Unless provided otherwise in the rules of an International Federation or ~~other relevant Anti-Doping Organization~~ 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.

~~International Event: An Event where the International Olympic Committee, the International Paralympic Committee, an~~

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

International-Level Athlete: Athletes ~~designated by one or more International Federations as being within the Registered Testing Pool for an~~ who compete in sport at the international level, as defined by each International Federation

~~International Standard: A standard adopted by WADA in support of the Code. Compliance with an International Standard (as opposed to another alternative standard, practice or procedure) shall be sufficient to conclude that the procedures addressed by the International Standard were performed properly. International Standards shall include any Technical Documents issued pursuant to the International Standard, 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 Committees and other international multi-sport organizations that function as the ruling body for any continental, regional or other International Event.

National Anti-Doping Organization: The entity(ies) designated by each country as possessing the primary authority and responsibility to adopt and implement anti-doping rules, direct the collection of Samples, the management of test results, and the conduct of hearings, ~~all~~ at the national level. ~~This includes an entity which may be designated by multiple countries to serve as regional Anti-Doping Organization for such countries.~~ 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 Event:** A-Level Athlete: Athletes who compete in sport Event involving international or national level Athletes that is not an International Event. at the national level, as defined by each National Anti-Doping Organization, consistent with the International Standard for Testing and Investigations.~~

~~**Out-of-Competition:** Any Doping Control which is not In-Competition.~~

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

~~[Comment to Possession: Under this definition, 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 shall 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 shall 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.]APP~~

~~–Definitions~~

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:** The pool of top-level Athletes established separately by each International Federation and National Anti-Doping Organization who are subject to both~~

~~In-Competition and Out-of-Competition Testing as part of that International Federation's or National Anti-Doping Organization's test distribution plan. Each International Federation shall publish a list which identifies those Athletes included in its Registered Testing Pool either by name or by clearly defined, specific criteria.~~

Signatories: Those entities signing the Code and agreeing to comply with the Code, ~~including the International Olympic Committee, International Federations, International Paralympic Committee, National Olympic Committees, National Paralympic Committees, Major Event Organizations, National Anti-Doping Organizations, and WADA.~~ 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.

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

Personal Information: ~~As defined in the International Standard for the Protection of Privacy and Personal Information, information,~~ including without limitation ~~sensitive~~Sensitive Personal Information, relating to an identified or identifiable *Participant* or relating to other *Persons* whose information is ~~processed~~Processed solely in the context of an *Anti-Doping Organization's* ~~anti-doping activities.~~ 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~~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.~~ 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.]

3.3 Further 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.

~~TUE: Therapeutic Use Exemption approved by a~~ **Therapeutic Use Exemption Committee** ~~based on a documented medical file and obtained before Use or Possession of, a substance or method that would otherwise be prohibited by the Code.~~ **TUEC: Therapeutic Use Exemption Committee is the (or "TUEC"):** The panel established by the relevant an Anti-Doping Organization to consider applications for TUEs.

WADA TUEC: ~~WADA Therapeutic Use Exemption Committee is the~~ The panel established by WADA, to review the TUE decisions of other Anti-Doping Organizations.

3.4 Interpretation:

3.4.1 Unless otherwise specified, references to articles are references to articles of the International Standard for Therapeutic Use Exemptions.

3.4.2 The comments annotating various provisions of the International Standard for Therapeutic Use Exemptions shall be used to interpret that International Standard.

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

PART TWO: STANDARDS AND PROCESS FOR GRANTING THERAPEUTIC USE EXEMPTIONS/TUES

~~4.0~~ Criteria for Granting a Therapeutic Use Exemption Obtaining a TUE

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

~~A Therapeutic Use Exemption (TUE) may be granted to an Athlete permitting the Use of a. The Prohibited Substance or Prohibited Method. An application for a TUE will be reviewed by a Therapeutic Use Exemption Committee (TUEC). The TUEC will be appointed by an Anti-Doping Organization.~~

~~4.1~~ ~~A TUE will be granted only in strict accordance with the following criteria:~~
~~a. The 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 in the course of treating an acute or chronic medical condition.~~

b. The Therapeutic Use of the Prohibited Substance or Prohibited Method ~~would~~ is highly unlikely to produce ~~no~~ any additional enhancement of performance ~~other than that which~~ beyond what might be anticipated by a return to ~~a~~ the Athlete's normal state of ~~normal~~ health following the treatment of ~~a legitimate medical condition. The Use of any Prohibited Substance or Prohibited Method to increase "low normal" levels of any endogenous hormone is not considered an acceptable Therapeutic intervention.~~ the acute or chronic medical condition.

c. There is no reasonable Therapeutic alternative to the Use of the ~~otherwise~~ Prohibited Substance or Prohibited Method.

d. The necessity for the Use of the ~~otherwise~~ Prohibited Substance or Prohibited Method ~~cannot be~~ 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.

~~4.2~~ ~~The TUE will be cancelled, if:~~

[Comment to 4.1: The WADA documents titled "Medical Information to Support the Decisions of TUECs", posted on WADA's website, should be used to assist in the application of these criteria in relation to particular medical conditions.]

4.2 Unless one of the exceptions set out in Article 4.3 applies, an *Athlete* who needs to Use a *Prohibited Substance* or *Prohibited Method* for Therapeutic reasons must obtain a *TUE* prior to Using or Possessing the substance or method in question.

4.3 An *Athlete* may only be granted retroactive approval for his/her Therapeutic Use of a *Prohibited Substance* or *Prohibited Method* (i.e., a retroactive *TUE*) if:

- a. Emergency treatment or treatment of an acute medical condition was necessary; or
- b. Due to other exceptional circumstances, there was insufficient time or opportunity for the Athlete to submit, or for the TUEC to consider, an application for the TUE prior to Sample collection; or
- c. The applicable rules required the Athlete (see comment to Article 5.1) or permitted the Athlete (see Code Article 4.4.5) to apply for a retroactive TUE; or

[Comment to 4.3(c): Such Athletes are strongly advised to have a medical file prepared and ready to demonstrate their satisfaction of the TUE conditions set out at Article 4.1, in case an application for a retroactive TUE is necessary following Sample collection.]

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

[Comment to 4.3(d): If WADA and/or the Anti-Doping Organization do not agree to the application of Article 4.3(d), that may not be challenged either as a defense to proceedings for an anti-doping rule violation, or by way of appeal, or otherwise.]

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 5.1: See Annex 1 for a flow-chart summarizing the key provisions of Code Article 4.4.]

Code Article 4.4.2 specifies the authority of a National Anti-Doping Organization to make TUE decisions in respect of Athletes who are not International-Level Athletes. In case of dispute as to which National Anti-Doping Organization should

deal with the TUE application of an Athlete who is not an International-Level Athlete, WADA will decide. WADA's decision will be final and not subject to appeal.

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

5.2 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 4.1.

[Comment to 5.2: 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 (such as Sport Accord). The aim in each case should be to ensure that Athletes competing in such Events have the ability to obtain TUEs quickly and efficiently before they compete.]

- a. 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. In cases involving Athletes with impairments, at least one TUEC member should possess general experience in the care and treatment of Athletes with impairments, or possess specific experience in relation to the Athlete's particular impairment(s).
- b. In order to ensure a level of independence of decisions, at least a majority of the members of a TUEC should have no political responsibility in the Anti-Doping Organization that appoints them. All members of the TUEC must sign a conflict of interest and confidentiality declaration. (A template declaration is available on WADA's website).

5.3 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.

5.4 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 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; and
- b. the TUE application form and the relevant clinical information (translated into English or French) establishing that the Article 4.1 conditions have been satisfied in respect of such TUE (for access only by WADA, the Athlete's National Anti-Doping Organization and International Federation, and the Major Event Organization organizing an Event in which the Athlete wishes to compete).

[Comment to 5.4: The process of recognition of TUEs is greatly facilitated by use of ADAMS.]

5.5 When a National Anti-Doping Organization grants a TUE to an Athlete, it must warn him/her in writing (a) that that TUE is valid at national level only, and (b) that if the Athlete becomes an International-Level Athlete or competes in an International Event, that TUE will not be valid for those purposes unless it is recognized by the relevant International Federation or Major Event Organization in accordance with Article 7.1. 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.

5.6 Each International Federation and Major Event Organization must publish a notice (at a minimum, by posting it in a conspicuous place on its website and sending it to WADA) that sets out clearly (1) which Athletes coming under its jurisdiction are required to apply to it for a TUE, and when; (2) which TUE decisions of other Anti-Doping Organizations it will automatically recognize in lieu of such application, in accordance with Article 7.1(a); and (3) which TUE decisions of other Anti-Doping Organizations will have to be submitted to it for recognition, in accordance with Article 7.1(b). WADA may re-publish the notice on its own website.

5.7 Any TUE that an Athlete has obtained from a National Anti-Doping Organization shall not be valid if the Athlete becomes an International-Level Athlete or competes in an International Event unless and until the relevant International Federation recognizes that TUE in accordance with Article 7.0. Any TUE that an Athlete has obtained from an International Federation shall not be valid if the Athlete competes in an International Event organized by a Major Event

Organization, 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 30 days before his/her next Competition, unless it is an emergency or exceptional situation. 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 template set out in Annex 2. The template may be modified by Anti-Doping Organizations to include additional requests for information, but no sections or items may be removed.

6.2 The Athlete should submit the TUE application form to the relevant Anti-Doping Organization via ADAMS or as otherwise specified by the Anti-Doping Organization. The form must be accompanied by:

- a. a statement by an appropriately qualified physician, attesting to the need for the Athlete to Use the Prohibited Substance or Prohibited Method in question for Therapeutic reasons; and
- b. a comprehensive medical history, including documentation from the original diagnosing physician(s) (where possible) and the results of all examinations, laboratory investigations and imaging studies relevant to the application.

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

6.3 The Athlete should keep a complete copy of the TUE application form and of all materials and information submitted in support of that application.

6.4 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.

6.5 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.

6.6 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.

6.7 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 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*.

6.8 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 or any other system approved by WADA, in accordance with Article 5.4.

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, as well as any conditions imposed in connection with the TUE.

b. A decision to deny a TUE application must include an explanation of the reason(s) for the denial.

6.9 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 6.9: The duration of validity should be guided by the WADA documents titled "Medical Information to Support the Decisions of TUECs".]

~~a. The~~ 6.10 A TUE will be withdrawn prior to expiry if the *Athlete* does not promptly comply with any requirements or conditions imposed by the *Anti-Doping Organization* granting the exemption. ~~TUE. Alternatively a TUE may be reversed upon review by WADA or on appeal.~~

~~b. The term for which the TUE was granted has expired.~~

~~c. The Athlete is advised that the TUE has been withdrawn by the Anti-Doping Organization.~~

~~d. A decision granting a TUE has been reversed by WADA or CAS.~~

~~{Comment: Each TUE will have a specified duration as decided upon by the TUEC. There may be cases when a TUE has expired or has been withdrawn and~~ 6.11 ~~Where an Adverse Analytical Finding is issued shortly after a TUE for the Prohibited Substance subject to the TUE is still present in the Athlete's body. In such cases in question has expired or has been withdrawn or reversed,~~ the *Anti-Doping Organization* conducting the initial review of ~~an~~ the *Adverse Analytical Finding*

~~will~~ (Code Article 7.2) shall consider whether the finding is consistent with Use of the Prohibited Substance prior to the expiry ~~or withdrawal of the TUE.~~, 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.

~~4.3~~ ~~An application for a TUE will not be considered for retroactive approval except in cases where:~~

- ~~a. Emergency treatment or treatment of an acute medical condition was necessary, or~~
- ~~b. Due to exceptional circumstances, there was insufficient time or opportunity for an applicant to submit, or a TUEC to consider, an application prior to Doping Control.~~

6.12 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 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.

7.0 TUE Recognition Process

7.1 ~~–[Comment: Medical emergencies or acute medical situations requiring administration of an otherwise Prohibited Substance or Prohibited Method before an application for a TUE can be made, are uncommon. Similarly, circumstances requiring expedited consideration of an application for a TUE due to imminent competition are infrequent. Anti-Doping Organizations granting TUEs should have internal procedures that permit such situations to be addressed.]–~~ Code Article 4.4 requires Anti-Doping Organizations to recognize TUEs granted by other Anti-Doping Organizations that satisfy the Article 4.1 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 5.4 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 at the time the TUE is granted, he/she does not need to take any further action.

[Comment to 7.1(a): To ease the burden on Athletes, automatic recognition of TUE decisions once they have been reported in accordance with Article 5.4 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 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 5.3, i.e., the notice should be posted on the International Federation's website and sent to WADA and to National Anti-Doping Organizations.]

b. In the absence of such automatic recognition, the Athlete shall submit a request for recognition of the TUE to the International Federation or Major Event Organization in question, either via ADAMS or as otherwise specified by that International Federation or Major Event Organization. The request should be accompanied by a copy of the TUE and the original TUE application form and supporting materials referenced at Articles 6.1 and 6.2 (unless the Anti-Doping Organization that granted the TUE has already made the TUE and supporting materials available via ADAMS or other system approved by WADA, in accordance with Article 5.4).

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 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 or any other system approved by WADA. A decision not to recognize a TUE must include an explanation of the reason(s) for the non-recognition.

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 conditions. WADA shall establish a WADA TUEC that meets the requirements of Article 5.2 to carry out such reviews.

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 6.2 (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 party 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 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 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 4.1 conditions were missing).

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 6.5, and/or it may obtain the assistance of other medical or scientific experts as it deems appropriate.

8.6 The WADA TUEC shall reverse any grant of a TUE that does not comply with the Article 4.1 conditions. Where the TUE reversed was a prospective TUE (rather than a retroactive TUE), such reversal shall take effect upon the date specified by WADA (which shall not be earlier than the date of WADA's notification to the Athlete). The reversal shall not apply retroactively and the Athlete's results prior to such notification shall not be Disqualified. Where the TUE reversed was a retroactive TUE, however, the reversal shall also be retroactive.

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

8.8 Where the WADA TUEC reviews a decision of an International Federation that has been referred to it pursuant to Code Article 4.4.3 (i.e., a mandatory review), it may require whichever Anti-Doping Organization “loses” the review (i.e., the Anti-Doping Organization whose view it does not uphold) (a) to reimburse the application fee to the party that referred the decision to WADA (if applicable); and/or (b) to pay the costs incurred by WADA in respect of that review, to the extent they are not covered by the application fee.

8.9 Where the WADA TUEC reverses a TUE decision that WADA has decided in its discretion to review, WADA may require the Anti-Doping Organization that made the decision to pay the costs incurred by WADA in respect of that review.

8.10 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).

~~5.0~~ Confidentiality of Information

8.2 ~~5.1~~ The collection, storage, processing, disclosure and retention of Personal Information ~~in~~ during the TUE process by Anti-Doping Organizations and WADA shall comply with the International Standard for the Protection of Privacy and Personal Information.

8.3 ~~5.2~~ An Athlete applying for the grant of a TUE or for recognition of a TUE shall provide written consent :

- a. for the transmission of all information pertaining to the application to members of all TUECs with authority under ~~the Code~~ 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 TUEs, and WADA. ~~The applicant shall also provide written consent for the decision of the TUEC to be distributed to other relevant TUE applications;~~
- b. for the Athlete’s physician(s) to release to the TUEC upon request any health information that the TUEC deems necessary in order to consider and determine the Athlete’s application; and
- c. for the decision on the application to be made available to all Anti-Doping Organizations ~~and National Federations under the provisions of the Code;~~ with Testing authority and/or results management authority over the Athlete.

[Comment to ~~5.29.2~~: Prior to collecting Personal Information or obtaining consent from an Athlete, the Anti-Doping Organization shall communicate to the Athlete the information set forth ~~out~~ in Article 7.1 of the International Standard for the Protection of Privacy and Personal Information.]

~~8.4~~ Should the assistance of external, independent experts be required, all details of the application will be circulated without identifying the Athlete concerned. The TUE application shall be dealt with in accordance with the principles of strict medical confidentiality.

~~5.3~~—The members of the ~~TUECs~~ TUEC, independent experts and the relevant staff of the Anti-Doping Organization ~~involved, will~~ shall conduct all of their activities relating to the process in strict confidence and ~~will~~ shall sign appropriate confidentiality agreements. In particular they ~~will~~ shall keep the following information confidential:

- a. All medical information and data provided by the Athlete and physician(s) involved in the Athlete's care.
- b. All details of the application, including the name of the physician(s) involved in the process.

~~8.5~~ Should the Athlete wish to revoke the right of ~~any~~ the TUEC to obtain any health information on his/her behalf, the Athlete shall notify his/her medical practitioner in writing of ~~the fact. As a consequence of such a decision, the Athlete will not receive approval for a TUE or renewal~~ 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.

~~5.4~~—

~~8.6~~ Anti-Doping Organizations shall ~~ensure that Personal Information obtained in the TUE process is retained for a period of eight (8) years, and thereafter only for as long as necessary to fulfill their obligations under the Code or where otherwise required by applicable law, regulation or compulsory legal process.~~

~~6.0 Therapeutic Use Exemption Committees (TUECs)~~

~~TUECs shall be constituted and act in accordance with the following guidelines:~~

~~6.1~~—~~TUECs should include at least three (3) physicians with experience in the care and treatment of Athletes and a sound knowledge of clinical, sports and exercise medicine. In order to ensure a level of independence of decisions, the majority of the members of any TUEC should be free of conflicts of interest or political responsibility in the Anti-Doping Organization. All members of a TUEC will sign a conflict of interest agreement. In applications involving Athletes with~~

disabilities, at least one TUEC member shall possess specific experience with ~~the care and treatment of Athletes with~~ disabilities.

~~6.2~~ ~~TUECs~~ may seek whatever medical or scientific expertise they deem appropriate in reviewing the circumstances of any application for a TUE.

~~6.3~~ The ~~WADA TUEC~~ shall be composed following the criteria set out in Article 6.1. The ~~WADA TUEC~~ is established to review the granting or denial of TUEs for ~~International Level Athletes, Athletes entered in an International event as described under 7.1(b), or Athletes in their National Anti-Doping Organization's Registered Testing Pool as set forth in Article 4.4 of the Code.~~ In normal circumstances, the ~~WADA TUEC~~ shall render a decision within 30 days of receipt of all requested information.—

~~**7.0 Responsibilities of International Federations and National Anti-Doping Organizations**~~

~~7.1~~ Each International Federation shall:

Establish a TUEC as provided in Article 6.

~~Publish a list of International Events for which a TUE granted pursuant to the International Federation's rules is required.~~

~~Establish and publish a TUE process whereby any Athlete who is in the International Federation's Registered Testing Pool or who is entered in an International Event described in Article 7.1(b) may request a TUE for a documented medical condition requiring the Use of a Prohibited Substance or a Prohibited Method. Such TUE process shall comply with Article 4.4 of the Code, this International Standard and the International Standard for the Protection of Privacy and Personal Information.~~

~~Publish any rule pursuant to which the International Federation will accept TUEs granted by other Anti-Doping Organizations.~~

~~Promptly report to WADA, through ADAMS, the granting of all TUEs, including the approved substance or method, dosage, frequency and route of administration, the duration of the TUE, any conditions imposed in connection with the TUE, and its entire file.~~

~~Promptly report the granting of a TUE to the relevant National Anti-Doping Organization and National Federation.~~

~~At WADA's request, promptly provide its entire file on any TUE which has been denied.~~

~~7.2~~ Each National Anti-Doping Organization shall:

Establish a TUEC as provided in Article 6.

~~Identify and publish those categories of *Athletes* within its jurisdiction who are required to obtain a TUE before *Using a Prohibited Substance or a Prohibited Method*.—At a minimum, this shall include all *Athletes* in the *National Anti-Doping Organization's Registered Testing Pool* and other national level *Athletes* as defined by the *National Anti-Doping Organization*.~~

~~Establish and publish a TUE process whereby any *Athlete* who is in the *National Anti-Doping Organization's Registered Testing Pool* or who is described in 7.2(b) may request a TUE for a documented medical condition requiring the *Use of a Prohibited Substance or a Prohibited Method*.—Such TUE process shall comply with Article 4.4 of the *Code*, this *International Standard* and the *International Standard for the Protection of Privacy and Personal Information*.~~

~~[Comment to 7.2(b):—National Anti-Doping Organizations will not grant TUEs to *Athletes* in an *International Federation's Registered Testing Pool* except in those instances where the *International Federation's* rules recognize or give authority to *National Anti-Doping Organizations* to grant TUEs to such *Athletes*.]~~

~~d. — Promptly report to *WADA*, through *ADAMS*, the granting of a TUE to any *Athlete* in its *Registered Testing Pool*, and if applicable, to an *Athlete* in an *International Federation's Registered Testing Pool* or entered in an *International Event* described in Article 7.1(b), including the approved substance or method, dosage, frequency and route of administration, the duration of the TUE, any conditions imposed in connection with the TUE, and its entire file.~~

~~e. — At *WADA's* request, promptly provide its entire file on any TUE that has been denied.~~

~~f. — Promptly report the granting of a TUE to the relevant *National Federation* and *International Federation* where the rules of the *International Federation* authorize *NADO* to grant TUEs to *International Level Athletes*.—~~

~~g. — Recognize TUEs granted by *International Federations* to *Athletes* in the *International Federation's Registered Testing Pool* or entered in an *International Event* as described under 7.1(b).~~

~~[As used in this Article 7, the term "publish" means:—An *Anti-Doping Organization* shall publish information by providing the information in a conspicuous place on its website and by sending the information to each *National Federation* which is subject to its rules.]~~

~~8.0 TUE Application Process~~

~~8.1~~ Unless the rules of their International Federation provide otherwise, the following *Athletes* shall obtain a TUE from their International Federation:

~~a.~~ *Athletes* in the International Federation's *Registered Testing Pool*;
and

~~b.~~ *Athletes* participating in an *International Event* for which a TUE granted pursuant to the International Federation's rules is required.

~~8.2~~ *Athletes* not identified in Article 8.1 shall obtain a TUE from their *National Anti-Doping Organization*.

[Comment to 8.1 and 8.2: Unless the rules of an International Federation provide otherwise, an Athlete who already has a TUE from a National Anti-Doping Organization, but later becomes a member of the International Federation's Registered Testing Pool or seeks to participate in an International Event which the International Federation has identified as requiring an International Federation TUE, shall obtain a new TUE from the International Federation.]

The phrase "unless the rules of an International Federation provide otherwise" takes into account the fact that some International Federations, through their rules, are willing to recognize TUEs granted by National Anti-Doping Organizations and do not require a new TUE application at the International Federation level. Where such rules are in place, the Athlete should obtain a TUE from the Athlete's National Anti-Doping Organization.]

~~8.3~~ The *Athlete* should submit an application for a TUE no less than thirty (30) days before he/she needs the approval (for instance, an *Event*).

~~8.4~~ A TUE will only be considered following the receipt of a completed application form that shall include all relevant documents (see Annex 1 TUE form). The application process shall be dealt with in accordance with the principles of strict medical confidentiality.

~~8.5~~ The TUE application form(s), as set out in Annex 1, can be modified by *Anti-Doping Organizations* to include additional requests for information, but no sections or items shall be removed.

~~8.6~~ The TUE application form(s) may be translated into other language(s) by *Anti-Doping Organizations*, but the English or French text shall remain on the application form(s).

~~8.7~~ The application shall identify the *Athlete's* level of competition (e.g., *International Federation Registered Testing Pool*), sport and, where appropriate, discipline and specific position or role.

~~8.8~~—The application shall list any previous and/or current TUE requests, the body to whom that request was made, the decision of that body, and the decisions of any other body on review or appeal.

~~8.9~~—The application shall include ~~a comprehensive medical history~~ and the results of all examinations, laboratory investigations and imaging studies relevant to the application. The arguments related to the diagnosis and treatment, as well as duration of validity, should be guided by the WADA “Medical Information to Support the Decisions of TUECs”.

~~8.10~~—Any additional relevant investigations, examinations or imaging studies requested by the TUEC of the *Anti-Doping Organization* before approval will be undertaken at the expense of the applicant.

[Comment to 8.10:—In some cases, the applicant’s National Federation may elect to pay this expense.]

~~8.11~~—The application shall include ~~a statement by an appropriately qualified physician~~ attesting to the necessity of the otherwise *Prohibited Substance* or *Prohibited Method* in the treatment of the *Athlete* and describing why an alternative, permitted medication cannot, or could not, be used in the treatment of this condition.

~~8.12~~—The substance or method, dose, frequency, route and duration of administration of the otherwise *Prohibited Substance* or *Prohibited Method* in question shall be specified. In case of change, a new application shall be submitted.

~~8.13~~—In normal circumstances, decisions of the TUEC should be completed within thirty (30) days of receipt of all relevant documentation and will be conveyed in writing to the *Athlete* by the relevant *Anti-Doping Organization*. In case of a TUE application made in a reasonable time limit prior to an *Event* the TUEC should use its best endeavors to complete the TUE process before the start of the *Event*.

[Comment to 8.13:—When an *Anti-Doping Organization* has failed to act on an *Athlete*’s TUE application within a reasonable time, the *Athlete* may seek review by WADA as if the application was denied.]

~~9.0 Declaration of Use~~

~~9.1~~ There are no longer substances or methods on the Prohibited List that require a Declaration of Use and therefore it is not necessary to file a Declaration of Use.

~~10.0 Review of TUE Decisions by WADA~~

~~10.1~~ The ~~WADA TUEC~~ may, at any time, review the grant of a ~~TUE~~ to an ~~Athlete~~ in the ~~International Federation Registered Testing Pool~~, entered in an ~~International Event~~ as described in 7.1(b), or a ~~National Anti-Doping Organization Registered Testing Pool~~. In addition to the information to be provided as set forth in Articles 7.1 and 7.2, the ~~WADA TUEC~~ may also seek additional information from the ~~Athlete~~, including further studies as described in Article 8.10. ~~If a decision granting a TUE is reversed by WADA upon review, the reversal shall not apply retroactively and shall not disqualify the Athlete's results during the period for which the TUE had been granted and shall take effect no later than fourteen (14) days following notification of the decision to the Athlete.~~

~~10.2~~ An ~~Athlete~~ in an ~~International Federation Registered Testing Pool~~, entered in an ~~International Event~~ as described in 7.1(b), or ~~National Anti-Doping Organization Registered Testing Pool~~ may request that ~~WADA~~ review the denial of a ~~TUE~~ by submitting a written request for review to ~~WADA~~ within twenty one (21) days of the date of the denial. ~~An Athlete~~ submitting such a request for review to ~~WADA~~ shall pay an application fee as established by ~~WADA~~ and shall provide to the ~~WADA TUEC~~ copies of all information that the ~~Athlete~~ submitted to the ~~Anti-Doping Organization~~ in connection with the ~~TUE~~ application. ~~The WADA TUEC~~ will assess the request based on the file that was available to the ~~Anti-Doping Organization~~ that has denied the ~~TUE~~ but may, for the sake of clarification, seek additional information from the ~~Athlete~~, including further studies as described in Article 8.10. Until the ~~WADA~~ review process has been completed, the original ~~TUE~~ denial remains in effect. ~~If WADA reverses the denial of a TUE, the TUE shall immediately go into effect in accordance with the conditions set forth in the WADA decision.~~

~~10.3~~ Decisions by ~~WADA~~ to affirm or reverse the ~~TUE~~ decisions of an ~~Anti-Doping Organization~~ may be appealed to ~~CAS~~ as provided in Article 13 of the ~~Code~~.

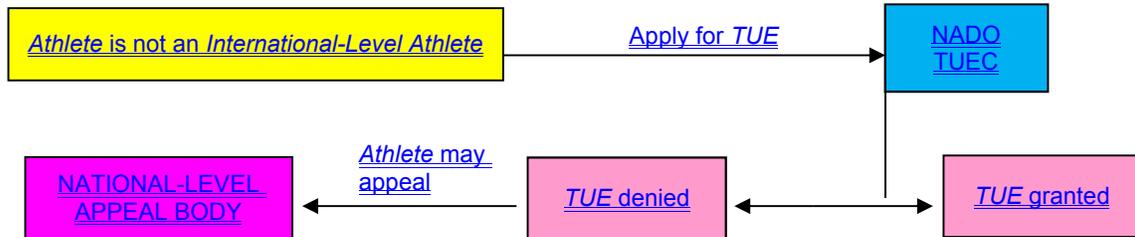
~~11.0 Previously Granted Abbreviated Therapeutic Use Exemptions (ATUEs)~~

~~11.1~~ All previously granted ATUEs that have not already expired or been cancelled shall expire on December 31, 2009.

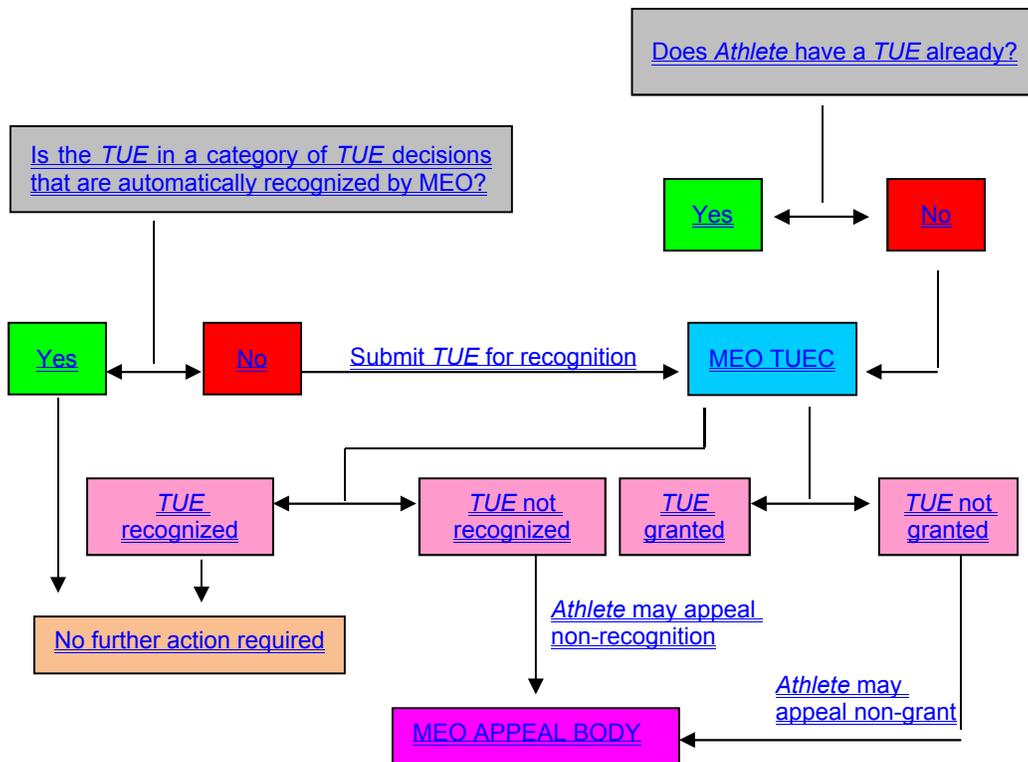
only use information submitted by an *Athlete* in connection with a *TUE* application to evaluate the application and in the context of potential anti-doping rule violation investigations and proceedings.

ANNEX 1: CODE ARTICLE 4.4 FLOW-CHART

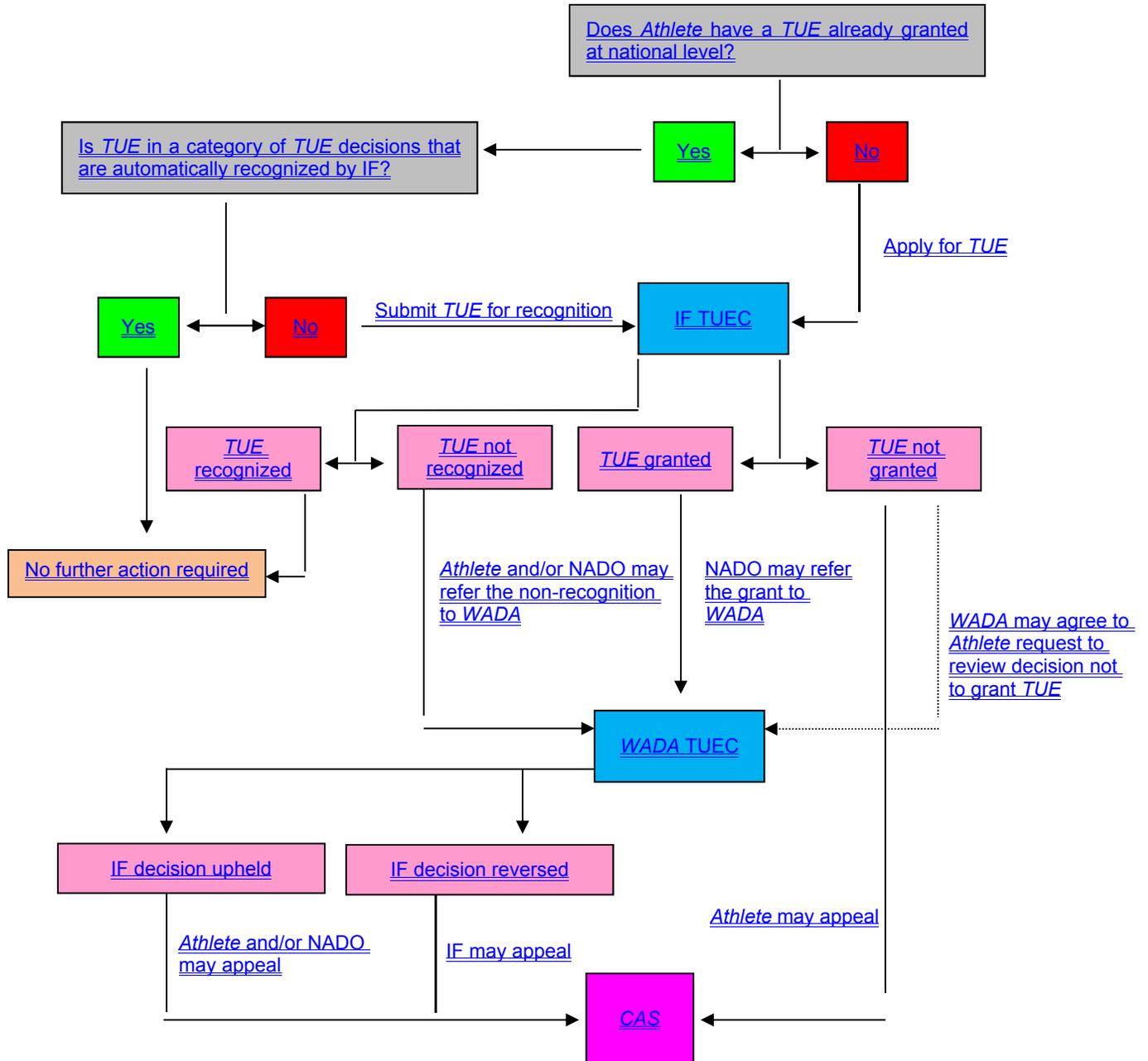
1. TUE procedure if Athlete is not an International-Level Athlete when need for TUE arises



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



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



ANNEX 2: TEMPLATE OF TUE APPLICATION FORM

~~Therapeutic use exemption application form~~

| |
|---|
| Identification of Anti-Doping Organization (Logo or Name of the ADO) |
|---|

~~Application form~~

~~THERAPEUTIC USE EXEMPTIONS TUE~~

Therapeutic Use Exemptions (TUE) APPLICATION FORM

Please complete all sections in capital letters or typing. Athlete to complete sections 1, 5, 6 and 7; physician to complete sections 2, 3 and 4. Illegible or incomplete applications will be returned and will need to be re-submitted in legible and complete form.

1. Athlete Information

| | | |
|--|-------------------------------|------------------------------|
| Surname: _____ | Given Names: _____ | |
| _____ | | |
| Female <input type="checkbox"/> | Male <input type="checkbox"/> | Date of Birth (d/m/y) _____: |
| Address: _____ | | |
| City: _____ | Country: _____ | |
| Postcode: _____ | | |
| Tel.: _____ | E-mail: _____ | |
| (with <i>international</i> <u>International</u> code) | | |
| Sport: _____ | Discipline/Position: _____ | |
| International or National Sport Organization: _____ | | |
| Please mark the appropriate box: | | |
| <input type="checkbox"/> I am part of an International Federation Registered Testing Pool | | |
| <input type="checkbox"/> I am part of a National Anti-Doping Organization Testing Pool | | |

I am participating in an International Federation event for which a TUE granted pursuant to the International Federation's rules is required[†] — Name of the competition: _____

None of the above

If ~~athlete~~you are an Athlete with ~~disability~~, an impairment, please indicate ~~disability~~the impairment:

[†] ~~Refer to your International Federation for the list of designated events~~

When?

~~approved~~

4. Medical practitioner's declaration

I certify that the information at sections 2 and 3 above is accurate, and that the above-mentioned treatment is medically appropriate ~~and that the use of alternative medication not on the prohibited list would be unsatisfactory for this condition.~~

Name:

Medical specialty:

Address: _____

Tel.: _____

Fax: _____

E-mail: _____

Signature of Medical Practitioner: _____

Date: _____

5. Retroactive applications

| | |
|---|--|
| <p><u>Is this a retroactive application?</u></p> <p><u>Yes:</u> <input type="checkbox"/></p> <p><u>No:</u> <input type="checkbox"/></p> <p><u>If yes, on what date was treatment started?</u></p> <p>_____</p> <p>_____</p> | <p><u>Please indicate reason:</u></p> <p><u>Emergency treatment or treatment of an acute medical condition was necessary</u> <input type="checkbox"/></p> <p><u>Due to other exceptional circumstances, there was insufficient time or opportunity to submit an application prior to sample collection</u> <input type="checkbox"/></p> <p><u>Advance application not required under applicable rules</u> <input type="checkbox"/></p> <p><u>Other</u> <input type="checkbox"/></p> <p><u>Please explain:</u></p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> |
|---|--|

6. Previous applications

| |
|---|
| <p><u>Have you submitted any previous TUE application(s)?</u> <u>Yes</u> <input type="checkbox"/></p> <p><u>No</u> <input type="checkbox"/></p> <p><u>For which substance or method?</u></p> <p>_____</p> <p><u>To whom?</u> _____ <u>When?</u> _____</p> <p><u>Decision:</u> <u>Approved</u> <input type="checkbox"/> <u>Not approved</u> <input type="checkbox"/></p> |
|---|

7. Athlete's declaration

I, _____, certify that the information ~~under 1 set out at sections 1, 5 and 6~~ is accurate ~~and that I am requesting approval to use a Substance or Method from the WADA Prohibited List~~. I authorize the release of personal medical information to the Anti-Doping Organization (ADO) as well as to WADA authorized staff, to the WADA TUEC (Therapeutic Use Exemption Committee) and to other ADO TUECs and authorized staff that may have a right to this information under the ~~provisions of the Code~~World Anti-Doping Code ("Code") and/or the International Standard for Therapeutic Use Exemptions.

I consent to my physician(s) releasing to the above persons any health information that they deem necessary in order to consider and determine my application.

I understand that my information will only be used for evaluating my TUE request and in the context of ~~possible~~potential anti-doping rule violation investigations and procedures. I understand that if I ever wish to (1) obtain more information about the use of my health information; (2) exercise my right of access and correction; or (3) revoke the right of these organizations to obtain my health information, I must notify my medical practitioner and my ADO in writing of that fact. I understand and agree that it may be necessary for TUE-related information submitted prior to revoking my consent to be retained for the sole purpose of establishing a possible anti-doping rule violation, where this is required by the *Code*.

I consent to the decision on this application being made available to all ADOs, or other organizations, with Testing authority and/or results management authority over me.

I understand and accept that the recipients of my information and of the decision on this application may be located outside the country where I reside. In some of these countries data protection and privacy laws may not be equivalent to those in my country of residence.

I understand that if I believe that my ~~personal information~~Personal Information is not used in conformity with this consent and the International Standard for the Protection of Privacy and Personal Information, I can file a complaint to WADA or CAS.

Athlete's signature: _____

Date:

Parent's/Guardian's signature: _____

Date:

(~~if~~If the ~~athlete~~Athlete is a ~~minor~~Minor or has a ~~disability~~an impairment preventing him/her to ~~sign~~signing this form, a parent or guardian shall sign ~~together with or~~ on behalf of the ~~athlete~~Athlete)

~~6. Note:~~

| | |
|---------------|---|
| Note 1 | <p>Diagnosis Evidence confirming the diagnosis shall be attached and forwarded with this application. The medical evidence should include a comprehensive medical history and the results of all relevant examinations, laboratory investigations and imaging studies. Copies of the original reports or letters should be included when possible. Evidence should be as objective as possible in the clinical circumstances and in the case of non-demonstrable conditions independent supporting medical opinion will assist this application.</p> |
|---------------|---|

Incomplete Applications will be returned and will need to be resubmitted.

Please submit the completed form to ~~the ADO~~ and keep by the following means (keeping a copy for your records):

Document comparison by Workshare Compare on Thursday, February 20, 2014
10:16:04 AM

| Input: | |
|---------------|---|
| Document 1 ID | file://H:\DOCUMENT COMPARE\ISTUE\English\ISTUE 2011.docx |
| Description | ISTUE 2011 |
| Document 2 ID | file://H:\DOCUMENT COMPARE\ISTUE\2015-ISTUE-Final-EN.docx |
| Description | 2015-ISTUE-Final-EN |
| Rendering set | Standard |

| Legend: | |
|---------------------------|--|
| <u>Insertion</u> | |
| Deletion | |
| Moved from | |
| <u>Moved to</u> | |
| Style change | |
| Format change | |
| Moved deletion | |
| Inserted cell | |
| Deleted cell | |
| Moved cell | |
| Split/Merged cell | |
| Padding cell | |

| Statistics: | |
|----------------------|------------|
| | Count |
| Insertions | 418 |
| Deletions | 333 |
| Moved from | 30 |
| Moved to | 30 |
| Style change | 0 |
| Format changed | 0 |
| Total changes | 811 |