



## **ELIGIBILITY REGULATIONS FOR TRANSGENDER ATHLETES**

*(Version 2.0, approved by Council on 23 March 2023, and coming into effect on 31 March 2023)*

## **General Information**

In the case of general queries regarding these Transgender Regulations, please contact:

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## 1. Introduction

- 1.1 World Athletics has adopted these Eligibility Regulations for Transgender Athletes (the “**Transgender Regulations**”) to facilitate the participation of Transgender athletes in the sport of Athletics in the classification that is consistent with their gender identity, in accordance with the following imperatives:
  - 1.1.1 World Athletics wants to give equal opportunities to all athletes to participate in and excel at the sport, and to provide them with fair and meaningful competition conditions, so that they are motivated to make the huge commitment and sacrifice required to excel in the sport, and so inspire new generations to join the sport and aspire to the same excellence.
  - 1.1.2 The substantial sex difference in sports performance that emerges from puberty onwards means that the only way to achieve the objectives set out above is to maintain separate classifications (competition categories) for male and female athletes. That difference is due to the physical advantages conferred on male athletes by the testes producing much higher levels of circulating testosterone than ovaries produce from puberty onwards in female athletes.
  - 1.1.3 World Athletics recognises that Transgender athletes may wish to compete in Athletics in a classification consistent with their gender identity. World Athletics respects the dignity of all individuals, including Transgender athletes. It also wishes the sport of Athletics to be as inclusive as possible, and to encourage and provide a clear path to participation in the sport for all. It therefore seeks to place conditions on such participation only to the extent necessary to deliver fair and meaningful competition conditions at the elite level of the sport.
  - 1.1.4 These Transgender Regulations exist solely to achieve the objectives set out above. In no way are they intended as any kind of judgement on or questioning of the gender identity of any athlete. On the contrary, the dignity and privacy of Transgender athletes must be respected and preserved, and therefore all cases arising under these Transgender Regulations must be handled and resolved in a confidential manner, recognising the sensitive nature of such matters.
- 1.2 These Transgender Regulations come into effect on 1 May 2023, replacing the previous edition of these Transgender Regulations (which came into effect on 1 October 2019), and apply immediately and in full to all cases falling within their scope. They will be subject to periodic review, and may be amended following such review to take account of any new evidence and/or relevant scientific or medical developments.
- 1.3 Since these Transgender Regulations apply globally, regulating the conditions for participation in competitions taking place around the world, insofar as is possible they are to be interpreted and applied not by reference to national or local laws, but rather as an independent and autonomous text, and in a manner that protects and advances the imperatives identified above. In the event that an issue arises that is not foreseen in these Transgender Regulations, it will be addressed by World Athletics in the same manner.
- 1.4 The words and phrases used in these Transgender Regulations that are defined terms (denoted by initial capital letters) have the meaning given to them in the Generally Applicable

Definitions section of the World Athletics Book of Rules, or else (if not defined there) have the following meanings:

**"Applicable Persons"** has the meaning given to that term in the Integrity Code of Conduct.

**"Competition Rules"** means the rules of that name included in the World Athletics Book of Rules, as amended from time to time.

**"Expert Panel"** has the meaning given to that term in Transgender Regulation 4.1.

**"Generally Applicable Definitions"** means the document of that name included in the World Athletics Book of Rules.

**"Medical Manager"** means a medically qualified person who is authorised by World Athletics to act on its behalf in matters arising under these Regulations.

**"Tanner Stages"** means the medical analysis that denotes the five stages of puberty during which individuals develop secondary sex characteristics. Tanner Stage 2 denotes the onset of puberty. The normal time of onset of puberty ranges from 8 to 13 years old in females, and from 9 to 14 years old in males.

**"Transgender"** means a person whose gender identity is different from their biological sex (whether they are pre- or post-puberty and whether or not they have undergone any form of medical intervention). A **"Transgender male"** is a person whose biological sex is female and whose gender identity is male; and a **"Transgender female"** is a person whose biological sex is male and whose gender identity is female. However, athletes who are Relevant Athletes – as that term is defined in the World Athletics Eligibility Regulations for the Female Classification (Athletes with Differences in Sex Development) – are excluded from this definition of Transgender, and their eligibility is governed by those regulations, not by these Transgender Regulations.

**"Transgender Female Eligibility Conditions"** has the meaning given to that term in Transgender Regulation 3.2.

**"Transgender Regulations"** has the meaning given to that term in Transgender Regulation 1.1.

**"World Record"** has the meaning given to that term in the Competition Rules.

1.5 The Rules of Interpretation in the World Athletics Book of Rules apply to these Transgender Regulations.

## 2. Application

2.1 A Transgender Athlete who wishes to be eligible to compete in the classification consistent with their gender identity at a World Rankings Competition, and/or if competing in a competition which is not a World Rankings Competition but who wishes to have a performance at that competition recognised as a World Record in such classification, agrees, as conditions to such eligibility:

2.1.1 to comply in full with these Transgender Regulations;

- 2.1.2 to cooperate promptly and in good faith with the Medical Manager and the Expert Panel in the discharge of their respective responsibilities under these Transgender Regulations, including:
    - 2.1.2.1 providing all of the information and evidence the Medical Manager and/or Expert Panel request to assess their compliance with these Transgender Regulations, including submitting to testing in accordance with these Transgender Regulations;
    - 2.1.2.2 ensuring that all information and evidence provided by them or on their behalf to the Medical Manager and/or the Expert Panel is accurate and complete, and that nothing relevant is withheld; and
    - 2.1.2.3 consenting to and ensuring the disclosure by their physician(s) to the Medical Manager and the Expert Panel of any information or evidence that the Expert Panel deems necessary to its assessment;
  - 2.1.3 (to the fullest extent permitted and not contrary to applicable laws) to the collection, processing, disclosure and use of information (including their sensitive personal information) as required to implement and apply these Transgender Regulations effectively and efficiently;
  - 2.1.4 to challenge these Transgender Regulations and/or to appeal decisions made under these Transgender Regulations only as set out in Transgender Regulation 7, and not to bring any proceedings in any court or other forum other than as prescribed in Transgender Regulation 7; and
  - 2.1.5 to provide written confirmation of their agreement with Transgender Regulations 2.1.1 to 2.1.4 upon request by World Athletics. However, their agreement to these Transgender Regulations will be assumed as an automatic consequence of their participation in Athletics and is effective and binding upon them whether or not confirmed in writing.
- 2.2 An Athlete may revoke at any time, without having to give reasons, the consent that they have granted further to Transgender Regulation 2.1. In that event, the Athlete will be deemed to have withdrawn any claim to satisfy the eligibility conditions for Transgender Athletes set out in Transgender Regulation 3.
- 2.3 Athletes, Athlete Representatives, Member Federations, Area Associations, Member Federation Officials, any other Applicable Person, and any other person who brings themselves under the jurisdiction of World Athletics by providing information to World Athletics pursuant to Transgender Regulation 2.6:
- 2.3.1 is bound by and must comply in full with these Transgender Regulations, including in particular only providing accurate and complete information, and not providing any information in bad faith or for any improper purpose; and
  - 2.3.2 must cooperate promptly and in good faith with the Medical Manager and the Expert Panel in the discharge of their respective responsibilities under these Transgender Regulations.

- 2.4 All cases arising under these Transgender Regulations will be dealt with by the World Athletics Health and Science Department, rather than by the Member Federation of the Athlete concerned (or by any other body), unless the Medical Manager specifically asks for their assistance with respect to a particular case. Each Member Federation must cooperate with and support World Athletics promptly and fully in the application and enforcement of these Transgender Regulations (including assisting upon request in respect of assessments and investigations conducted under these Transgender Regulations), must observe strictly the confidentiality obligations set out below, and must ensure that any Transgender Athlete under its jurisdiction that is entered to compete in World Rankings Competitions is eligible to do so under these Transgender Regulations.
- 2.5 A Member Federation may adopt its own regulations to determine the eligibility of Transgender Athletes to compete in competitions taking place under its own jurisdiction that are not World Rankings Competitions. For the avoidance of doubt, however:
- 2.5.1 Nothing that the Member Federation does or does not do at national level will affect the eligibility of Transgender Athletes to compete in World Rankings- Competitions or to have recognised a World Record in a competition that is not a World Rankings Competition. That eligibility will instead be determined exclusively by reference to these Transgender Regulations.
- 2.5.2 If a Member Federation decides to allow a Transgender athlete to compete in competitions under its jurisdiction in the classification that is consistent with their gender without having to meet the requirements of these Transgender Regulations, World Athletics will not recognise the athlete's performances for World Records or World Rankings purposes, and will list their results separately.
- 2.6 At the request of an Athlete whose case arises for investigation and/or assessment under these Transgender Regulations, World Athletics will appoint an independent ombudsperson to help the Athlete to understand and address the requirements of the Transgender Regulations, and will pay the costs charged by the ombudsperson for providing such assistance.
- 2.7 The dignity of every individual must be respected. All forms of abuse and/or harassment are prohibited. In particular (but without limitation):
- 2.7.1 Any person or entity that provides information to the Medical Manager and/or the Expert Panel for consideration under these Transgender Regulations must:
- 2.7.1.1 ensure that the information is accurate and complete; and
- 2.7.1.2 not provide any information in bad faith, to harass, stigmatise or otherwise injure an Athlete, or for any other improper purpose.
- 2.7.2 No stigmatisation or improper discrimination on grounds of gender identity will be tolerated. In particular, persecution of or campaigns against an Athlete simply on the basis that their appearance does not conform to gender stereotypes are unacceptable. Any such conduct will be considered a serious breach of these Transgender Regulations and of the Integrity Code of Conduct, as will any breach of the confidentiality provisions set out below.

- 2.8 For purposes of these Transgender Regulations, all measurements of serum testosterone must be conducted by means of liquid chromatography coupled with mass spectrometry.

### **3. Eligibility Conditions for Transgender Athletes**

#### **3A. Eligibility conditions for Transgender male Athletes**

- 3.1 To be eligible to compete in the male classification at a World Rankings Competition or to have recognised any World Record performance in the male classification in a competition that is not a World Rankings Competition, a Transgender male Athlete must provide a written and signed declaration, in a form satisfactory to the Medical Manager, that their gender identity is male. As soon as reasonably practicable following receipt of such declaration, the Medical Manager will issue a written certification of that Athlete's eligibility to compete in the male classification in World Rankings Competitions and to have recognised any World Record performance in the male classification in a competition that is not a World Rankings Competition.

#### **3B. Eligibility conditions for Transgender female Athletes**

- 3.2 To be eligible to compete in the female classification at a World Rankings Competition and to have recognised any World Record performance in the female classification at a competition that is not a World Rankings Competition, a Transgender female Athlete must meet each of the following conditions (together, the “**Transgender Female Eligibility Conditions**”) to the satisfaction of the Expert Panel:

- 3.2.1 They must provide a written and signed declaration, in a form satisfactory to the Medical Manager, that their gender identity is female.
- 3.2.2 They must not have experienced any part of male puberty either beyond Tanner Stage 2 or after age 12 (whichever comes first).
- 3.2.3 Since puberty they must have continuously maintained the concentration of testosterone in their serum below 2.5 nmol/L.
- 3.2.4 They must continue to maintain the concentration of testosterone in their serum below 2.5 nmol/L at all times (i.e., whether they are in competition or out of competition) for so long as they wish to retain eligibility to compete in the female classification at World Rankings Competitions and/or have recognised any World Record performance in the female classification at a competition that is not a World Rankings Competition.

#### **3C. Provisions applicable to all Transgender Athletes**

- 3.3 For the avoidance of doubt:
- 3.3.1 No Athlete will be forced to undergo any medical assessment and/or treatment under these Transgender Regulations. It is the Athlete's responsibility, in close consultation with their medical team, to decide on the advisability of proceeding with any assessment and/or treatment.
- 3.3.2 There are no other special conditions (i.e., other than the Transgender Female Eligibility Conditions) that a Transgender Athlete must satisfy in order to compete at

World Rankings Competitions and/or have recognised any World Record performance at other competitions in the classification consistent with their gender identity. In particular, the following are not required in order for a Transgender Athlete to be eligible to compete in a World Rankings Competition, and have recognised any World Record performance in a competition that is not a World Rankings Competition, in the classification consistent with their gender identity:

3.3.2.1 legal recognition of the Athlete's gender identity; or

3.3.2.2 surgical anatomical changes.

3.3.3 The eligibility conditions for Transgender Athletes set out in these Transgender Regulations operate without prejudice to the other eligibility requirements that are applicable to all Athletes (Transgender or otherwise) under the rules of World Athletics. Those other eligibility requirements must also be satisfied at all relevant times. In particular, nothing in these Transgender Regulations is intended to undermine or affect in any way any of the requirements of the World Anti-Doping Code, of the WADA International Standards (including the International Standard for Therapeutic Use Exemptions), or of the World Athletics Anti-Doping Rules. Nothing in these Transgender Regulations permits, excuses, or justifies non-compliance with any of those requirements, including any requirement for an Athlete to obtain a therapeutic use exemption for the use of substances on the WADA Prohibited List, such as testosterone, spironolactone, or GnRH agonists.<sup>1</sup>

3.4 Once a Transgender Athlete has satisfied the relevant eligibility requirements set out above and has started competing in World Rankings Competitions in the sex classification that is consistent with their gender identity, they may not then participate in the other sex classification in World Rankings Competitions, or have recognised any World Record performance in the other sex classification in a competition that is not a World Rankings Competition, unless and until (a) at least four years have passed since the last World Rankings Competitions in which they competed as a Transgender Athlete; and (b) they satisfy all of the conditions for eligibility to compete in the other sex classification.

#### **4. Assessment of Cases**

4.1 World Athletics' Chief Executive Officer (or their designee) will appoint a pool of independent medical experts from which a suitably qualified panel of experts (the "**Expert Panel**") may be formed to review cases arising under these Transgender Regulations. They will also designate one of those experts to act as chair and to select the Expert Panel for each case. The chair and other independent medical experts appointed by World Athletics to this pool as of the date of entry into force of these Transgender Regulations are identified in Appendix 2.

4.2 The Expert Panel may make such enquiries or investigations as it considers necessary to carry out its assessments accurately and effectively, including requesting further information from the Athlete or the Athlete's physicians and/or obtaining additional expert opinion(s). The Athlete is responsible for ensuring that the information provided is accurate and complete, and that nothing relevant to the Expert Panel's assessment of the case is withheld. The Athlete must also provide the appropriate consents and waivers (in a form satisfactory to the Medical

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<sup>1</sup> See further the WADA Transgender Athletes TUE Physician Guidelines, available at [www.wada-ama.org](http://www.wada-ama.org).



Manager) to enable the athlete's physicians to disclose to the Medical Manager and the Expert Panel any information that the Expert Panel deems necessary to its assessment.

#### **4A. Opening a case**

4.3 A Transgender female Athlete who wishes to be declared eligible to compete in the female classification at a World Rankings Competition, and/or to have recognised any World Record performance in the female classification in a competition that is not a World Rankings Competition:

4.3.1 must file the declaration referred to at Transgender Regulation 3.2.1 with the Medical Manager;

4.3.2 must provide a comprehensive medical history, including details of:

4.3.2.1 any reassignment surgeries the Athlete has undertaken, including the date(s) of any such procedures and whether they took place before or after puberty;

4.3.2.2 any other relevant treatment the Athlete has received (including pre- or post-reassignment treatment), including the timing, dosage, and frequency of such treatment; and

4.3.2.3 the results of any pre- or post-reassignment monitoring;

4.3.3 save where they can prove to the satisfaction of the Medical Manager that they have had a gonadectomy or other procedure that will have necessarily and permanently suppressed their testosterone below 2.5 nmol/L:

4.3.3.1 must give the Medical Manager advance notice of their whereabouts, in the manner and by the means specified by the Medical Manager (which may involve, for example, providing the Medical Manager with the same whereabouts information as the Athlete files under applicable anti-doping rules), so that the Medical Manager is able to locate them for the purposes of sample collection without advance notice at any time;

4.3.3.2 must provide samples on demand to a service provider engaged by the Medical Manager, in accordance with sample collection procedures prescribed by the Medical Manager to safeguard the identity and integrity of the samples;

4.3.3.3 consents to the Medical Manager having those samples analysed to assess the Athlete's compliance with the requirements of Transgender Regulations 3.2.3 and 3.2.4; and

4.3.3.4 agrees to advise the Medical Manager of the results of analysis of samples collected from the Athlete under applicable anti-doping rules (or, if they do not have that information, agrees to do everything in their

power to ensure that the person holding that information provides it to the Medical Manager).

- 4.4 The Athlete is responsible for ensuring that the information provided is accurate and complete, and that nothing relevant to the Expert Panel's assessment of the case is withheld. The Athlete must also provide the appropriate consents and waivers (in a form satisfactory to the Medical Manager) to enable the Athlete's physicians to disclose to the Medical Manager and the Expert Panel any information that the Expert Panel deems necessary to its assessment.
- 4.5 After communicating with the Athlete and/or the Athlete's physicians to remedy any obvious deficiencies, the Medical Manager will refer the file (in anonymised form) to the Expert Panel, together with details of the steps that the Medical Manager proposes to take to monitor the levels of testosterone in the Athlete's serum, and will amend those proposed steps as necessary to address any comments made by the Expert Panel.

#### **4B. Investigations**

- 4.6 A Member Federation must promptly advise the Medical Manager of any relevant information derived from a reliable source that indicates that an Athlete under its jurisdiction is or may be a Transgender Athlete to whom these Transgender Regulations apply. The Medical Manager will investigate and progress such cases as they see fit.
- 4.7 In addition, provided they are acting in good faith and on reasonable grounds based on information derived from reliable sources (for example, the Athlete, the team doctor of the Member Federation to which the Athlete is affiliated, results from a routine pre-participation health examination, and/or information/data (including but not limited to serum testosterone levels) obtained from the collection and analysis of samples from the Athlete for anti-doping purposes), the Medical Manager may investigate whether an Athlete who is competing or is or may be entered to compete at a World Rankings Competition may be a Transgender Athlete to whom these Transgender Regulations apply.
- 4.8 The Medical Manager may also investigate, at any time:
- 4.8.1 whether (because of a subsequent change in circumstances, subsequent learning, or experience, or otherwise) it is necessary to require a Transgender Athlete who has previously been determined to satisfy the Transgender Female Eligibility Conditions to undergo further assessment by the Expert Panel to determine whether they still satisfy those conditions; and/or
- 4.8.2 any circumstances that indicate potential non-compliance by a Transgender Athlete with these Transgender Regulations.
- 4.9 The Athlete in question must cooperate fully and in good faith with the investigation by the Medical Manager and any subsequent assessment by the Expert Panel, including by providing serum and/or urine samples upon request for analysis, and/or submitting to medical examination).
- 4.10 Where the Athlete does not cooperate as required under Transgender Regulation 4.9 or otherwise as required by these Transgender Regulations, or where otherwise necessary to safeguard the fairness and/or integrity of competition, World Athletics may provisionally suspend the Athlete from competing in World Rankings Competitions, and from being eligible to set a World Record in any competition that is not a World Rankings Competitions, pending

resolution of the matter. Where such provisional suspension is imposed, all reasonable endeavours must be used to complete the investigation and assessment as expeditiously as possible. Any such provisional suspension may be appealed in accordance with Transgender Regulation 7.2.2.

- 4.11 Where the Medical Manager concludes following an investigation that an Athlete is a Transgender Athlete to whom these Transgender Regulations apply, the Medical Manager will invite the Athlete to provide the information set out in Transgender Regulation 4.2 so that their case may be assessed.

#### **4C. Expert Panel assessment**

- 4.12 The Expert Panel will assess cases referred to it by the Medical Manager to determine whether the Transgender Female Eligibility Conditions have been met (or, if not, then what else the Athlete must do if they wish to satisfy those conditions). It will base its assessment on the guidance set out in Appendix 1. It may make such enquiries or investigations as it considers necessary to carry out the assessment accurately and effectively, including requesting further information from the Athlete or the Athlete's physician and/or obtaining additional expert opinion(s).

- 4.13 If the Expert Panel has any concerns about the adequacy of any of the information provided by or on behalf of the Athlete, it will give the Athlete a fair opportunity to address those concerns before it comes to its final decision.

- 4.14 Once it has completed its assessment, the Expert Panel will send its decision in writing to the Medical Manager, who will forward it to the Athlete (with a copy to the Athlete's physician and the Athlete ombudsperson, if any).

4.14.1 If the Expert Panel decides that the evidence provided is not sufficient to demonstrate that the Transgender Female Eligibility Conditions have been met, it must explain in writing the reasons for its decision. Where applicable, it should also specify what else the Athlete needs to do to satisfy those conditions (including, for example, monitoring; reporting; further reviews).

4.14.2 If the Expert Panel decides that the Transgender Female Eligibility Conditions have been met, the Medical Manager will issue a written certification of that Athlete's eligibility to compete in the female classification in World Rankings Competitions and to have recognised any World Record performance in the female classification in a competition that is not a World Rankings Competition. That eligibility will be conditional in every case on the Athlete continuing to maintain their serum testosterone at a concentration of less than 2.5 nmol/L.

- 4.15 The Expert Panel's decision will be final and binding on all parties. It may only be challenged by way of appeal in accordance with Transgender Regulation 7.

#### **5. Continuing Compliance**

- 5.1 A Transgender female Athlete will be solely responsible for maintaining the concentration of testosterone in their serum at less than 2.5 nmol/L for as long as they wish to be eligible to compete in the female classification at World Rankings Competitions and/or to have recognised a World Record performance in the female classification at any competition that is not a World Rankings Competition.

- 5.2 The Expert Panel may specify particular means of demonstrating such continuing compliance. In any event, the Athlete must produce, on request, evidence satisfactory to the Medical Manager of such continuing compliance. In particular, save where the Athlete can prove to the satisfaction of the Expert Panel that they have had a gonadectomy or other procedure that will have necessarily and permanently suppressed their testosterone below 2.5 nmol/L, the Medical Manager:
- 5.2.1 may require the Athlete to provide ongoing evidence of the concentration of testosterone in their serum, such as laboratory reports obtained by their personal physician of the results of analysis of samples collected periodically from the Athlete;
  - 5.2.2 may monitor the concentration of testosterone in the Athlete's system, including by having samples collected from the Athlete and analysed for relevant evidence;
  - 5.2.3 may consult with the chair of the Expert Panel at any stage during this process as the Medical Manager considers necessary; and
  - 5.2.4 may refer the Transgender female Athlete back to the Expert Panel for further assessment.
- 5.3 To facilitate the Medical Manager's monitoring of a Transgender female Athlete's testosterone levels under Transgender Regulation 5.2, the Athlete:
- 5.3.1 must give the Medical Manager advance notice of their whereabouts, in the manner and by the means specified by the Medical Manager (which may involve, for example, providing the Medical Manager with the same whereabouts information as the Athlete files under applicable anti-doping rules), so that the Medical Manager is able to locate the Athlete for purposes of sample collection at any time without having to give advance notice;
  - 5.3.2 must submit to collection of samples of their serum and/or urine on demand by a service provider engaged by the Medical Manager, in accordance with sample collection procedures prescribed by the Medical Manager to safeguard the identity and integrity of the samples;
  - 5.3.3 consents to the Medical Manager having those samples analysed to assess the Athlete's compliance with the requirements of these Transgender Regulations; and
  - 5.3.4 agrees to advise the Medical Manager of the results of analysis of samples collected from the Athlete under applicable anti-doping rules (or, if they do not have that information, agrees to do everything in their power to ensure that the person holding that information provides it to the Medical Manager) for purposes of assessing their compliance with the requirements of these Transgender Regulations.
- 5.4 If a Transgender female Athlete who has previously been declared eligible to compete in the female classification in World Rankings Competitions:
- 5.4.1 refuses or fails without compelling justification to comply with one or more of the requirements of Transgender Regulation 5.3; or

5.4.2 is found (whether by sample analysis or otherwise) to have failed to keep the concentration of testosterone in their serum below 2.5 nmol/L;

then (subject always to Transgender Regulation 5.5):

5.4.2.1 where World Athletics' Chief Executive Officer (or their nominee) considers it necessary to do so to maintain the integrity of competition results, they may disqualify the individual results obtained by the Athlete in the female classification at World Rankings Competitions and/or other competitions, with all resulting consequences, including forfeiture of any medals, ranking points, prize money, records (including World Records), and other items awarded to the Athlete based on those results;

5.4.2.2 where the Athlete is able to satisfy the Expert Panel on the balance of probabilities that their failure to keep the concentration of testosterone in their serum below 2.5 nmol/L was unintentional, the Athlete will be ineligible to compete in the female classification in World Rankings Competitions or to have recognised a World Record performance in the female classification in a competition that is not a World Rankings Competition for such period (if any) as the Expert Panel shall consider necessary to protect fair competition in the female classification; and

5.4.2.3 where the Athlete is not able to satisfy the Expert Panel on the balance of probabilities that their failure to keep the concentration of testosterone in their serum below 2.5 nmol/L was unintentional, the Athlete will be ineligible to compete in the female classification in World Rankings Competitions or to have recognised a World Record performance in the female classification in a competition that is not a World Rankings Competition for the same period as the period of ineligibility that they would have received for intentional use of an anabolic steroid under the World Athletics Anti-Doping Rules in force at the relevant time. The Athlete will be given a reasonable opportunity to provide any explanations or comments they see fit before any results are disqualified or any period of ineligibility is imposed pursuant to Transgender Regulation 5.4.

5.5 Any decision to disqualify results and/or to impose a period of ineligibility pursuant to Transgender Regulation 5.4 may be appealed by the Athlete in question in accordance with Transgender Regulation 7.

## **6. Disciplinary Proceedings**

6.1 Without prejudice to the powers given to World Athletics in Transgender Regulations 4.11 and 5.4, where:

6.1.1 a Transgender Athlete competes in a World Rankings Competition in a classification for which they have not satisfied the eligibility conditions set out in these Transgender Regulations; or

6.1.2 an Applicable Person has been complicit in a breach of or non-compliance with these Transgender Regulations by an Athlete; or

- 6.1.3 there has been any other breach of or non-compliance by an Applicable Person with these Transgender Regulations;

such breach of these Transgender Regulations amounts to a breach of the Integrity Code of Conduct and will accordingly be subject to investigation by the Athletics Integrity Unit under the Athletics Integrity Unit Reporting, Investigation and Prosecution Rules (Non-Doping) and possible prosecution before the World Athletics Disciplinary Tribunal in accordance with the Disciplinary Tribunal Rules.

- 6.2 In such disciplinary proceedings, the validity of these Transgender Regulations or of any decision made under these Transgender Regulations may not be challenged. Instead, such challenge may only be brought by way of challenge or appeal in accordance with Transgender Regulation 7.

- 6.3 In such disciplinary proceedings, the sanctions that may be imposed in case of proven breach may include (depending on all of the circumstances of the case):

6.3.1 a caution, reprimand, and/or warning as to future conduct;

6.3.2 the disqualification of individual results obtained by the Athlete at World Rankings Competitions, with all resulting consequences, including forfeiture of any medals, ranking points, prize money, or other items awarded to the Athlete based on those results;

6.3.3 the disqualification of a World Record set at a competition that is not a World Rankings Competition;

6.3.4 a specified period of ineligibility of the Athlete to participate in World Rankings Competitions; and/or

6.3.5 a fine.

- 6.4 Where a Member Federation has failed to comply in full with these Transgender Regulations, and/or has failed to ensure compliance in full by Athletes under its jurisdiction with these Transgender Regulations, World Athletics may take action against that Member Federation in accordance with its powers under the Constitution.

## **7. Dispute Resolution**

- 7.1 Excluding the disciplinary matters referenced in Transgender Regulation 6 (which will be addressed as set out in that regulation), any dispute arising between World Athletics and an Athlete (and/or their Member Federation) in connection with these Transgender Regulations will be subject to the exclusive jurisdiction of the CAS. In particular, the validity, legality, and/or proper interpretation and application of these Transgender Regulations may only be challenged (a) by way of ordinary proceedings filed before the CAS; and/or (b) as part of an appeal to the CAS made pursuant to Transgender Regulation 7.2.

- 7.2 The following decisions (and only the following decisions) made under these Transgender Regulations may be appealed by the Athlete who is the subject of the decision to the CAS in accordance with this Transgender Regulation 7, by filing a Statement of Appeal with the CAS and with World Athletics (as the respondent to the appeal) within thirty days of the date of receipt of the written reasons for the decision:

- 7.2.1 a decision that the Athlete does not comply with the requirements of these Transgender Regulations and therefore is not eligible to compete in World Rankings Competitions (or to have a World Record recognised in other competitions) in the classification that is consistent with their gender identity;
  - 7.2.2 a decision pursuant to Transgender Regulation 4.11 to suspend an Athlete provisionally from competition; and
  - 7.2.3 a decision pursuant to Transgender Regulation 5.4 to disqualify results and/or to impose a period of ineligibility.
- 7.3 Any such challenge or appeal will be conducted in the English language and will be governed by the Constitution, these Transgender Regulations, and the other applicable rules and regulations of World Athletics, with the laws of Monaco applying subsidiarily. The CAS will hear and determine the challenge or appeal definitively in accordance with the CAS Code of Sports-Related Arbitration, provided that (1) in the event of any conflict between the aforementioned governing instruments and laws on the one hand and the CAS Code of Sports-Related Arbitration on the other hand, the governing instruments and laws will take precedence; and (2) in any appeal the Athlete will have fifteen days from the filing of the Statement of Appeal to file their Appeal Brief, and World Athletics will have thirty days from its receipt of the Appeal Brief to file its Answer. Pending determination of the challenge or appeal, the Transgender Regulations and the decision under appeal will remain in full force and effect, unless the CAS orders otherwise.
- 7.4 The decision of the CAS on the merits of the challenge or appeal will be final and binding on all parties, and no right of appeal or other challenge will lie from that decision on any ground, except as set out in Chapter 12 of the Swiss Federal Code on Private International Law.

## **8. Confidentiality**

- 8.1 All cases arising under these Transgender Regulations, and in particular all information relating to an Athlete that is provided to World Athletics under these Transgender Regulations, and all results of examinations and assessments conducted under these Transgender Regulations, must be maintained in strict confidence at all times. All medical information and data relating to an Athlete will be treated as sensitive personal information, and the Medical Manager must ensure that it is processed as such in accordance with applicable data protection and privacy laws. Such information and data may not be used for any purpose that is not contemplated in these Transgender Regulations, and may not be disclosed to any third party save (a) as is strictly necessary for the effective application and enforcement of these Transgender Regulations; or (b) as is required by law.
- 8.2 World Athletics will not comment publicly on the specific facts of a case arising under these Transgender Regulations (as opposed to general descriptions of the process and science involved) except in response to public comments made by the Athlete or the Athlete's representatives.
- 8.3 Each member of the Expert Panel must sign an appropriate conflict of interest declaration and confidentiality undertaking in relation to their work as a member of the panel.

## **9. Costs**

- 9.1 World Athletics will bear the costs of assessment of the Athlete under these Transgender Regulations (including the standing costs of the Expert Panel and all costs of the doctors and experts involved in such assessment), as well as the costs of collecting samples from the Athlete to monitor their compliance with the requirements of these Transgender Regulations.
- 9.2 The Athlete will bear the costs of their personal physician(s) and of any treatment prescribed for them by their personal physician(s), including any treatment required to satisfy the requirements of these Transgender Regulations, as well as any other costs of demonstrating compliance with these Transgender Regulations that are not paid by World Athletics pursuant to Transgender Regulation 9.1.

## **10. Mutual Recognition**

- 10.1 Where a Transgender athlete from another sport wishes to participate in the sport of Athletics, World Athletics may recognise and give effect to the eligibility decision of the international federation of the other sport in relation to that athlete, provided that the eligibility decision and the regulations of that other sport relating to that eligibility decision are consistent with these Transgender Regulations. Any eligibility so afforded shall be subject to ongoing compliance by the athlete with the requirements of these Transgender Regulations.

## **11. Limitation of Liability**

- 11.1 In no circumstances will World Athletics, any member of the Expert Panel, or any of World Athletics' employees, officers, agents, representatives, and other persons involved in the application and/or enforcement of these Transgender Regulations be liable in any way to any person in relation to acts done or omitted to be done in good faith in connection with these Transgender Regulations.
- 11.2 Each case will be addressed as quickly as is reasonably practicable in all of the circumstances. However, in no circumstance will World Athletics or the Medical Manager or any member of the Expert Panel be liable for any detriment allegedly suffered by the Athlete in question or anyone else as a result of the length of time taken to complete the investigation/assessment of their case.



## APPENDIX 1: MEDICAL GUIDELINES

### Contents

1. **General background medical information**
2. **Guidance on monitoring serum testosterone levels in transgender female athletes for eligibility purposes**
3. **Guidance on the method for measuring serum testosterone levels for eligibility purposes**

The application of the Transgender Regulations will necessarily be highly individualised and specific to the circumstances of the particular case. These medical guidelines are only intended to provide some general guidance on certain medical aspects of the Transgender Regulations, to assist with their application in practice. All information detailed in this Appendix 1 is based on existing literature applicable to such cases, and neither World Athletics nor any of its employees, officers, agents, representatives, or other persons involved in the administration of these Transgender Regulations shall be held liable in any way for any results obtained by the procedures adopted.

### **1. General Background Medical Information**

- 1.1 Gender identity refers to an individual's self-perceived gender. This may be different to the individual's sexual anatomy, chromosomal, gonadal or hormonal sex, gender role or sex recorded at birth.
- 1.2 Because some children who present as transgender will not in fact do so as adults, early medical treatment carries significant risk. The issue is problematic because individuals who wish to avail themselves of transgender treatment will find it easier at a younger age, prior to the need to reverse opposite sex characteristics developed in puberty. A paradigm to address the tension is to use GnRH analogs (or progestins) that delay puberty in a reversible fashion until a longer-term plan is in place. GnRH analogs would be started at the first visible signs of puberty or approximately Tanner 2. Note that pre-pubertal children do not require any medical intervention.

#### **Diagnosis**

- 1.3 Diagnosis of transgender identity is usually straightforward among adults. Whether or not a given individual with a transgender identity wants to address the incongruence is a very personal decision and may be influenced by a variety of factors.
- 1.4 In order to avoid a psychiatric condition confounding the situation to such a degree that gender identity is not clear, a mental health provider is normally included on the medical management team to confirm the absence of such a confounder and to assist with transition-related stress (which can be significant).

#### **Medical treatment**

- 1.5 For transgender individuals who seek medical intervention, the most effective treatment strategy is generally to change the individual's appearance to align with their gender identity.

- 1.6 The mainstay of medical treatment is hormone therapy. Many transgender individuals will also seek gender-affirming surgical interventions, with choices influenced by (among other things) access to care, technical aspects of the specific surgeries, and personal elements that must be customised to the specific patient.
- 1.7 Hormone treatment of transgender individuals follows conventional hormone paradigms, with the same concerns and effects as are seen when using the same hormones for other purposes.
- 1.8 It is also important for transgender athletes to consider whether any medical treatment sought requires them to obtain a Therapeutic Use Exemption for the use of a substance on the WADA Prohibited List (such as testosterone, spironolactone or GnRH agonists). Further information can be found in the WADA Transgender Athletes TUE Physician Guidelines, available at [www.wada-ama.org](http://www.wada-ama.org).

#### Transgender male treatment strategy and typical regimens

- 1.9 Typically, hormone treatment for transgender men consists of administration of testosterone to bring the serum testosterone level up from the female range (0.06 to 1.68 nmol/L (95% two-sided confidence limit)) to the male range (7.7 to 29.4 nmol/L (95% two-sided confidence limit)). The doses required are similar to those used for treatment of hypogonadal males. Testosterone is administered parenterally (either intramuscularly or subcutaneously) or transdermally (via gel, solution or patch).
- 1.10 A typical testosterone regimen is as follows:

#### Parenteral

- Testosterone esters (enanthate, cypionate, mixed): 50 – 250 mg IM or SC every 1-3 weeks
- Testosterone undecanoate: 750 or 1000 mg every 8-12 or 10-14 weeks

#### Transdermal

- Testosterone gel, cream or solution: 50 – 100 mg/day
- Testosterone transdermal patch: 2.5 – 7.5 mg/day

- 1.11 Most transgender men who seek medical intervention will also want chest reconstruction surgery (mastectomy). However, most transgender men will not seek genital reconstruction surgeries (phalloplasty or metoidioplasty) because of the high rate of complications, the cost (in countries where it is not part of general healthcare), and the potential for multiple surgeries (Kailas et al, Endocr Pract. 2017; 23).
- 1.12 Transgender treatment guidelines have expressed concern of possible malignancy risk in female reproductive tissues exposed to androgens for long periods. This is one reason why transgender men have commonly elected to have hysterectomy and oophorectomy early in treatment. However, because there are no data demonstrating the cancer risk, there has been a downward trend in the frequency of such surgeries.

#### Transgender female treatment strategy and typical regimens

- 1.13 For transgender women, the strategy is to decrease serum testosterone levels from the male range to the female range. Although more invasive than medicine alone, the easiest way to

achieve the goal is with a gonad-removing surgery (orchidectomy, which may or may not be part of a genital reconstruction surgery, i.e. vaginoplasty), followed by age-appropriate estrogen replacement therapy to feminise and to protect bone health over time.

- 1.14 For transgender women treated medically, the typical hormone treatment consists of estrogen supplementation and an androgen-lowering or -blocking agent.
- 1.15 Multiple estrogen options exist. The most popular are 17 beta estradiol and conjugated estrogens (although these are not used in Europe). Depending on the individual, doses may be double to quadruple those typically given to post-menopausal women. The doses sometimes need to be higher still for individuals with testes present in order to reduce serum testosterone levels to the female range.
- 1.16 There are reports that the thrombogenicity of estrogens can be mitigated if oral administration is avoided. Although the data are not conclusive, transdermal and injectable estrogens are recommended in some countries. While transdermal estradiol is easy to monitor, injectable estradiol is more difficult to monitor than oral estrogens. The strongest data regarding estrogens relate to increased thrombogenicity with oral ethinyl estradiol specifically. Therefore, current guidelines discourage its use in favor of the other agents available.
- 1.17 One anti-androgen is spironolactone, used because of its long-term safety profile arising from its 50-year history as a potassium-sparing diuretic to treat hypertension. Higher doses are used than are required for blood pressure control, with doses of approximately 200 mg/day not unusual and doses as high as 400 mg/day sometimes observed (in divided doses if needed for the patient to tolerate).
- 1.18 Another commonly used anti-androgen is cyproterone acetate. Cyproterone acetate is more expensive in some countries than spironolactone, and it is not available at all in some countries. Recently, cyproterone acetate has been associated with slight elevations in prolactin levels not observed with other androgen-lowering agents.
- 1.19 A third anti-androgen is depot GnRH agonist therapy, used for transgender children following the regimens typical for precocious puberty. However, GnRH agonist therapy can be very effective in lowering serum testosterone levels for adult transgender women as well. There are no long-term safety data for GnRH therapy in such patients. Its use is further limited by being substantially more expensive than either spironolactone or cyproterone acetate, as well as being administered parenterally, whereas the other two are administered orally.
- 1.20 Some transgender women may also use the androgen-blocking drug finasteride, a 5 $\alpha$ -reductase inhibitor that (among other things) is intended to mitigate male-pattern baldness.
- 1.21 A typical regimen for transgender women is as follows:

### ***Estrogens***

#### ***Transdermal***

- Estradiol transdermal patch: 0.025 – 0.2 mg/day (new patch placed 1-2 times per week)
- Estradiol gel: 1 – 2 mg/day

### Parenteral

- Estradiol valerate or cypionate: 2 – 30 mg IM every 1-2 weeks
- Polyestradiol phosphate: 80 mg every 3-4 weeks

### Oral

- Estradiol: 2.0 – 8.0 mg/day
- Conjugated estrogens: 2.5 – 10.0 mg/day

### **Testosterone lowering or blocking agents**

- Spironolactone: 100 – 400 mg/day
- Cyproterone acetate: 25 – 50 mg/day
- GnRH agonist: 3.75 – 11.25 mg SC monthly (longer interval regimens are common too)
- Finasteride: 1 – 5 mg/day

- 1.22 Many transgender women will supplement medical treatment with gender-affirming surgeries such as (1) facial feminisation surgeries (especially sought by transgender women transitioning later in life after having been exposed to male androgen levels for a longer time period); (2) breast augmentation surgery; and (3) genital reconstruction surgery. Although society has tended to focus on genital surgery as the defining gender-affirming surgery, transgender individuals demonstrate great heterogeneity in surgical choices. Notably, less surgery may be sought than previously expected, and a higher priority than commonly appreciated may be placed on visible surgeries like facial feminisation procedures and breast augmentation rather than on genital surgeries (Kailas et al, *Endocr Pract.* 2017; 23).

### **Monitoring of medical treatment**

#### Transgender male monitoring

- 1.23 One concern about testosterone therapy is an increase in haematocrit (with a possible increased thrombosis risk). This risk is greatest with excessive testosterone dosage. Patients may also be advised to be aware of mood changes.
- 1.24 The typical monitoring regime includes indicated clinical examination, including blood pressure and laboratory testing, every 3 months when making changes to the regimen and then every 6-12 months thereafter. Usual monitoring includes measurement of serum testosterone (to determine success of therapy), haematocrit, and lipid profile.
- 1.25 Malignancy screening must include all body parts present regardless of whether or not they are associated with one sex or another (for example, Pap smears and mammograms for transgender men who still have cervix and breasts, respectively).

#### Transgender female monitoring

- 1.26 The biggest concern for estrogen therapy is an increased thrombosis risk, which can lead to deep venous thromboses, pulmonary embolism, or stroke. There are no data for other estrogen-dependent health concerns, although many practitioners monitor classic estrogen-sensitive laboratory values including prolactin.

- 1.27 Anti-androgen therapy of any sort may result in decreased libido. Spironolactone is a potassium-sparing diuretic, which means that sensitive individuals may have unacceptable rises in their potassium levels.
- 1.28 Usual monitoring of transgender female hormone regimens includes measurement of serum testosterone (to determine success of therapy), estrogen level (estradiol), prolactin, potassium (if spironolactone is used). The typical monitoring regime includes indicated clinical examination and laboratory testing every 3 months when making changes to the regimen, and then every 6-12 months thereafter.
- 1.29 Malignancy screening must include all body parts present regardless of whether or not they are associated with one sex or another (including prostate cancer surveillance even for transgender women who have had genital reconstruction surgery).

### References

- 1.30 The following (non-exhaustive) references may be of interest:
- Fung et al, *Differential Effects of Cyproterone Acetate vs Spironolactone on Serum High-Density Lipoprotein and Prolactin Concentrations in the Hormonal Treatment of Transgender Women*, J Sex Med 2016; 13: 1765e1772.
  - Hembree et al, *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline*, J Clin Endocrinol Metab, November 2017, 102(11):1–35.
  - Irwig, *Testosterone therapy for transgender men*, Lancet Diabetes Endocrinol. 2017; Apr;5(4):301-311.
  - Kailas et al, *Prevalence And Types Of Gender-Affirming Surgery Among A Sample Of Transgender Endocrinology Patients Prior To State Expansion Of Insurance Coverage*, Endocr Pract. 2017; 23.
  - Mamoojee, Yaasir et al, *Transgender hormone therapy: understanding international variation in practice*, The Lancet Diabetes & Endocrinology, Volume 5, Issue 4, p243-246, April 2017.
  - Saraswat et al, *Evidence Supporting the Biologic Nature of Gender Identity*, Endocr Pract. 2015; 21: 199-204.
  - World Professional Association for Transgender Health, Standards of Care, available at [www.wpath.org](http://www.wpath.org).
  - [www.uptodate.com/contents/transgender-men-evaluation-and-management](http://www.uptodate.com/contents/transgender-men-evaluation-and-management)
  - [www.uptodate.com/contents/transgender-women-evaluation-and-management](http://www.uptodate.com/contents/transgender-women-evaluation-and-management)

## **2. Guidance On Monitoring Serum Testosterone Levels In Transgender Female Athletes For Eligibility Purposes**

- 2.1 As discussed above, for transgender women there are several different treatment strategies to decrease serum testosterone from the male range to the female range (the most definitive being gonad-removing surgery). The typical clinical monitoring regime is detailed above.
- 2.2 For eligibility purposes, the Transgender Regulations authorise World Athletics to monitor an athlete's compliance with the Transgender Female Eligibility Conditions at any time, with or without notice, whether by random or targeted testing of the athlete's serum testosterone levels, or by any other appropriate means.
- 2.3 Monitoring programmes will necessarily be highly individualised and specific to the circumstances of the particular case and should be established with the support of an endocrinologist/gynaecologist or a hormone-prescribing physician experienced in the field. Particular factors to consider might include:
  - Whether the athlete is pre- or post-puberty.
  - Whether the athlete has undergone orchidectomy.
  - The type of medical treatment used by the athlete. For example, an orchidectomised athlete may require only a limited amount of monitoring. Athletes using daily estrogen medications (oral, transdermal) that have short-term testosterone suppressive effects may require unannounced testing from time to time, whereas depot estradiol implants require less surveillance due to their longer duration of action. Similarly, athletes using daily oral spironolactone or cyproterone acetate in the form of oral daily capsules will likely need to be monitored more closely than athletes using depot gonadotropin-releasing hormone (GnRH) agonists administered every 1-3 months.
  - The physiological demands of the sport and the likely performance-enhancing effect of testosterone.
  - Other information collected during the course of establishing and maintaining eligibility (for example, any evidence of medication non-compliance, previous loss of eligibility, or other risk factors).
- 2.4 In some cases, the laboratory data obtained from an athlete's routine clinical follow-up might provide an acceptable or sufficient level of monitoring. In other cases, additional monitoring may be required.

## **3. Guidance on The Method for Measuring Serum Testosterone Levels For Eligibility Purposes**

- 3.1 For purposes of the Transgender Regulations, all measurements of serum testosterone levels must be conducted by means of liquid chromatography coupled with mass spectrometry (e.g. LC-MS/MS or LC-HRMS), which provides much better specificity than traditional immunoassay methods.
- 3.2 The method used must be validated by the laboratory carrying out the test and must also be accredited to the ISO/IEC-17025 or 15189 international standards by a recognised accreditation body that is a full member of the International Laboratory Accreditation Cooperation (ILAC).

These requirements may be met by clinical laboratories as well as by WADA-accredited laboratories.

- 3.3 The method used must comply with assay performance criteria, including a measurement uncertainty (estimated during method validation at testosterone concentration levels close to the threshold of 2.5 nmol/L) of not more than 20%.
- 3.4 The performance of the method must be monitored through participation of the performing laboratory in appropriate proficiency testing (PT) and/or external quality assessment scheme (EQAS) round(s).
- 3.5 Serum samples should be collected using standardised sample collection procedures (for example, those used for anti-doping purposes). Such procedures might include the following:
  - It is recommended that samples are collected in the morning (as testosterone concentration in serum decreases during the day).
  - Venous blood should be collected, with the athlete remaining in a normal seated position with feet on the floor for at least ten minutes prior to providing the sample. Samples should not be collected within two hours of any physical exertion.
  - A collection tube containing a clotting agent and a gel separator should be used e.g. BD Vacutainer SST-II Advance (a single sample only will be sufficient, but World Athletics may decide to collect a reserve sample as well, at its discretion).
  - The sample should be transported to the laboratory in a refrigerated state. The sample should not be allowed to freeze, and temperature should preferably be maintained in the range 2-12°C (ideally around 4°C). A temperature data logger should be used to record the temperature of the sample during transport.
  - The sample should arrive at the laboratory within 48 hours of sample collection. The sample should be centrifuged as soon as possible on arrival and stored frozen if it cannot be analysed immediately.

**APPENDIX 2: EXPERT PANEL**

	<b>Name</b>	<b>Area of expertise</b>
1	Prof. Joshua Safer (USA) Chair	Endocrinology, Transgender Medicine
2	Prof. Angelica Lindén Hirschberg (SWE)	Gynecology/endocrinology
3	Prof. Natalie Nokoff (USA)	Pediatrics/endocrinology
4	Prof. Lourdes Ibáñez Toda (ESP)	Pediatrics/endocrinology
5	Prof. Jeffrey D. Zajac (AUS)	Pediatrics/endocrinology