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Athlete Passport Management Unit

Requirements and Procedures

1.0 Introduction

This <u>Technical Document</u> has been established to harmonize effective management of <u>Athlete Passports</u> by providing specific requirements that an <u>Athlete Passport Management Unit (APMU)</u> shall meet in order to be a <u>WADA</u> approved <u>APMU</u>.

2.0 APMU Roles and Responsibilities

- 2.1 The <u>APMU</u> is the dedicated unit that is responsible for the timely management of <u>Passports</u> in the Anti-Doping Administration and Management System (*ADAMS*) on behalf of the <u>Passport Custodian</u>. <u>Passport</u> management by the <u>APMU</u> involves:
 - a) Performing <u>Passport</u> assessments to make timely <u>Target Testing</u> recommendations to the <u>Anti-Doping Organization</u> (ADO) via the <u>APMU Report</u> in <u>ADAMS</u> when appropriate; and
 - b) Managing the review of atypical <u>Passports</u> according to Annex L of the International Standard for Testing and Investigations (ISTI), including, but not limited to, the following:
 - Issuing and updating <u>APMU Reports</u> in *ADAMS*,
 - In case of an Atypical Passport Finding (ATPF), or when a review is otherwise justified, assigning and liaising with the <u>Expert</u> panel as required,
 - Compiling all necessary information to establish an <u>Athlete</u> <u>Biological Passport (ABP) Documentation Package</u>, and
 - Declaring Adverse Passport Findings (APFs) to the <u>Passport</u> <u>Custodian</u> and WADA.
- 2.2 The <u>APMU</u> shall assess and manage <u>Passport</u> <u>Sample</u> validity in <u>ADAMS</u>, in consultation with the <u>Experts</u> or <u>Laboratories</u> when necessary per Article 8.2 of this Technical Document.
- 2.3 The <u>APMU</u> shall provide support to the <u>Passport Custodian</u> in defining priorities in order to optimize the efficiency of their *ABP* program. These priorities may include, but are not limited to, cost efficiency, special analyses, <u>Test Distribution Plans</u>, and *Target Testing*.

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3.0 APMU Hosting

- 3.1 An <u>APMU</u> shall be hosted by a <u>Laboratory</u>. 1
- 3.2 <u>APMU</u> hosting by a <u>Laboratory</u> does not preclude the use of qualified <u>APMU</u> managers employed by *ADOs* or other <u>Laboratories</u>.
- 3.3 <u>Passport</u> management shall be carried out in *ADAMS* using dedicated <u>APMU</u> accounts associated with the host <u>Laboratory</u> regardless of the physical location of the <u>APMU</u> manager(s).
- 3.4 The host <u>Laboratory</u> shall implement procedures to maintain the operational independence of the <u>APMU</u>, including the appointment of dedicated personnel with a specified time commitment to the <u>APMU</u> and a separate allocation in the budget so that the <u>APMU</u> can continue to function should the *WADA* accreditation of the <u>Laboratory</u> be suspended (see 7.1.5 below).

4.0 APMU Personnel

- 4.1 Personnel employed by, or under contract to, the <u>APMU</u> shall have a personal file which shall contain copies of the curriculum vitae or qualification form, a job description, and records of initial and ongoing training related to anti-doping. The <u>APMU</u> shall maintain appropriate confidentiality of <u>Personal Information</u>.
- 4.2 All personnel shall have a thorough knowledge of their responsibilities including respect of the confidentiality of results, the procedures for the management of *Sample* validity and compilation of <u>ABP Documentation Packages</u>, and the <u>Passport review process</u>.
- 4.3 The host <u>Laboratory</u> shall have a *Person* qualified to function as the designated head of the <u>APMU</u>² by assuming professional, organizational, educational, and administrative responsibility of the <u>APMU</u>. The <u>APMU</u> director is responsible for ensuring the <u>APMU</u> operates in compliance with this <u>Technical Document</u> and applicable *International Standards*. In particular, the <u>APMU</u> director assumes the responsibility of signing and delivering all *APFs* to the <u>Passport Custodian</u> and *WADA*.

¹ Hosting in this context is defined as the provision of facilities and resources for the efficient functioning of the <u>APMU</u>.

² The head of the APMU is termed "director" herein, however use of this title is not a requirement and can be adjusted according to the needs of the organization.

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- 4.3.1 The <u>APMU</u> director's qualifications shall ensure that he or she is competent and capable of leading the <u>APMU</u> operations, including:
 - A doctoral degree (or equivalent) in one of the natural sciences or medicine, or in the absence of a doctoral degree, a master's degree (or equivalent) with extensive and appropriate anti-doping science experience and training (i.e., minimum of five (5) years);
 - Management experience;
 - Ability to oversee compliance with quality management practices; and
 - Good command of at least one of WADA's two official languages, English and French.

It is acknowledged that the <u>APMU</u> director plays an essential role in the <u>APMU</u> operations and that <u>WADA APMU</u> approval is delivered based upon appointment of a proper candidate. <u>WADA</u> reserves the right to review the credentials of such appointment in accordance with the above qualifications.

Any personnel changes to the position of <u>APMU</u> director shall be communicated to *WADA* no later than one month prior to the scheduled date the <u>APMU</u> director vacates his/her position. A succession plan shall be submitted to *WADA*.

The <u>APMU</u> director is notably responsible for monitoring the quality of <u>Passport</u> management and ensuring that other <u>APMU</u> personnel have the experience and training necessary to perform their duties.

4.4 The <u>APMU</u> shall use qualified scientific personnel to serve as <u>APMU</u> manager(s)³ to manage the <u>Passport</u> review process and <u>Sample</u> validity, and to provide <u>Target Testing</u> and <u>Analytical Testing</u> recommendations through <u>APMU Reports</u> in <u>ADAMS</u>. <u>APMU manager(s)</u> shall be employed by the host <u>Laboratory</u> or be under contract by an <u>ADO</u> or another <u>Laboratory</u>.⁴ The <u>APMU should have at least one <u>APMU manager</u> per Module of the <u>ABP</u>.</u>

³ The designation of "manager" is used herein, however use of this title is not a requirement and can be adjusted according to the needs of the organization. The <u>APMU</u> director can also serve in the role of <u>APMU</u> manager as required.

⁴ An individual <u>APMU</u> manager may be contracted by multiple <u>APMUs</u> concurrently. Where the <u>APMU</u> manager is employed by an *ADO*, it is assumed that this individual will have access to the identity and other privileged or confidential information about the *Athlete*, past *Testing* and/or results management and investigations history. This additional information shall not be shared by the <u>APMU</u> manager in the <u>APMU Report</u>, but is recognized to be important to contribute to effective *Target Testing*.

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- 4.4.1 <u>APMU</u> manager(s) shall have qualifications in one or more Modules of the *ABP*. The qualifications are at minimum:
 - Bachelor's degree (or equivalent) in one of the natural or health sciences.
 Documented experience of three (3) years or more in anti-doping or similar scientific training is equivalent to a Bachelor's degree for this position; and
 - Adequate training in one or more Modules of the ABP, capacity to understand and evaluate analytical results and the physiological response to the Use of Prohibited Substances and Prohibited Methods, as well as criteria relevant for Target Testing.
- 4.4.2 Where the <u>APMU</u> manager has strong qualifications in <u>Laboratory</u> steroid analysis, steroid doping and metabolism and/or clinical endocrinology, and is not employed by the <u>Passport Custodian</u>, the <u>APMU</u> manager can act as a first <u>Expert</u> for the Steroidal Module of the *ABP*.
- 4.5 The <u>APMU</u> should have administrative personnel to coordinate with the <u>Passport Custodian</u> to compile the necessary documentation required for the <u>ABP Documentation Packages</u>, manage communication with various stakeholders and assist with the organization of APMU-related documentation.

5.0 APMU Confidentiality and Security

- 5.1 All <u>APMU</u> related activities shall be carried out in accordance with the confidentiality requirements of the *Code* and *International Standards*. <u>Personal Information</u> shall be maintained in strict confidence in accordance with the International Standard for the Protection of Privacy and Personal Information (ISPPPI) and applicable national and regional laws.
- 5.2 The <u>APMU</u> shall have a policy to ensure the confidentiality of its procedures and security of its information systems regardless of the physical location of the <u>APMU</u> personnel at the time of <u>Passport</u> management, such as when the <u>APMU</u> manager is physically located in an *ADO*, another <u>Laboratory</u> or when travelling.
- 5.3 The <u>APMU</u> shall have a policy for the security of its activities and information systems against unauthorized access. Such policy should be based on a threat and risk assessment by expert(s) in the relevant field.
- 5.4 The <u>APMU</u> shall adhere to those information retention times set forth in Annex A of the ISPPI. In consultation with the <u>Passport Custodian</u>, the <u>APMU</u> shall develop

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specific plans and procedures to ensure the secure retention and eventual destruction of Personal Information.

6.0 ABP Expert Panel

- 6.1 The <u>APMU</u> shall engage the services of qualified <u>Experts</u> for the review of Passports in accordance with Annex L of the ISTI.
- 6.2 The <u>APMU</u> shall establish, in consultation with the *ADO*, a list of <u>Experts</u> who are qualified to comprise an <u>Expert</u> panel for the review of <u>Passports</u> for which the *ADO* is the <u>Passport Custodian</u>.
 - For the Haematological Module, the <u>Expert</u> panel should consist of at least three (3) <u>Experts</u> who have qualifications in one or more of the fields of clinical and laboratory haematology, sports medicine and exercise physiology, as they apply to blood doping.
 - For the Steroidal Module, the <u>Expert</u> panel should be composed of at least three (3) individuals with qualifications in the fields of <u>Laboratory</u> steroid analysis, steroid doping and metabolism and/or clinical endocrinology.
 - All three (3) <u>Experts</u> forming an <u>Expert</u> panel assigned to review a
 particular <u>Passport</u> shall not be of one and the same nationality and no
 two (2) <u>Experts</u> shall have a primary affiliation with the same
 organization, institution or company, including, but not limited to,
 universities, hospitals and research institutes.
 - At least one <u>Expert</u> on the <u>Expert</u> panel shall currently serve, or have previously served as an <u>Expert</u> and reviewed <u>Passports</u> for a <u>WADA-approved APMU</u>.
- 6.3 The APMU shall ensure that each Expert:
 - receives relevant ABP <u>Expert</u> education resources provided by WADA; and,
 - has an <u>Expert</u> account created in *ADAMS* by the <u>APMU</u> for the anonymous review of Passports.
 - is independent of the <u>Passport Custodian</u> and has been requested to declare all potential conflicts of interest in reviewing <u>Passports</u>⁵, and

⁵ An <u>APMU</u> manager may also concurrently serve as an <u>Expert</u> for other <u>APMUs</u>, provided all requirements of Article 6.0 are met.

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has signed the WADA ABP <u>Expert</u> Code of Conduct. The ABP <u>Expert</u> Code of Conduct is provided in Appendix A of this <u>Technical Document</u>.

7.0 Process and Requirements for WADA APMU Approval

Passports shall only be managed by APMUs that have been approved by WADA.

7.1 Applying for WADA APMU Approval

7.1.1 Expression of interest

The candidate <u>APMU</u> shall officially contact *WADA* in writing to express its interest in the *WADA* <u>APMU</u> approval process.

7.1.2 Preliminary discussion with WADA

The purpose of this discussion is to clarify issues with regard to the approval process and to obtain information about different aspects of the <u>APMU</u> relevant to the approval process. Such a discussion could be conducted prior to or during the approval process.

7.1.3 Description of the candidate APMU

The candidate <u>APMU</u> shall then complete a detailed application form provided by *WADA* and submit it to *WADA* no later than eight (8) weeks following receipt. The application form includes, but is not limited to, the following:

- List of staff, their qualifications and intended role within the APMU;
- Description of physical facilities, including a description of the security considerations for records and computer systems;
- List of external Experts, their contact information, and their qualifications;
- Business plan for the <u>APMU</u> and letters of support from *ADOs* that demonstrate a commitment to manage⁶ a minimum of 100 haematological <u>Passports</u> and 500 steroidal <u>Passports</u> from <u>Codecompliant Testing Authorities</u> (as determined by <u>WADA</u>) annually, within one year of receiving approval. An eligible business plan shall demonstrate a commitment to provide at least 200 <u>APMU Reports</u> for

⁶ See Article 2.0 for a description of the role of the APMU in Passport management.

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haematological <u>Passports</u> and 500 <u>APMU Reports</u> for steroidal <u>Passports</u> per year.

7.1.4 Liability insurance coverage

The <u>APMU</u> shall provide documentation to *WADA* that professional liability risk insurance coverage or equivalent has been obtained which covers the <u>APMU</u> to an amount of no less than 2 million USD annually, and should ensure that the <u>Expert</u> panel has suitable professional liability risk insurance or equivalent coverage.

7.1.5 Operational independence

The <u>APMU</u> shall ensure a degree of operational independence from the host <u>Laboratory</u> such that the <u>APMU</u> can continue to fulfill its responsibilities in compliance with this <u>Technical Document</u> should the <u>WADA</u> accreditation of the <u>Laboratory</u> be suspended, where the reason for the <u>Suspension</u> does not have an impact on the function of the <u>APMU</u>. Operational independence implies that the <u>APMU</u> shall have a separate allocation in the budget and sufficient technical and human resources to permit the <u>APMU</u> to manage its own affairs without hindrance or interference by host Laboratories.

7.1.6 Compliance with the WADA APMU Code of Ethics

The candidate <u>APMU</u> shall implement and comply with the provisions in the <u>WADA APMU</u> Code of Ethics (Appendix B). The <u>APMU</u> shall provide the <u>APMU</u> Code of Ethics to <u>APMU</u> personnel and ensure their understanding and compliance with all aspects. The candidate <u>APMU</u> shall provide to <u>WADA</u> a letter of compliance with the <u>APMU</u> Code of Ethics, signed by the <u>APMU</u> director.

7.1.7 WADA recommendation for approval

After receipt of the application form, *WADA* will complete and submit a report to the candidate <u>APMU</u>. The report will include a recommendation concerning approval of the candidate <u>APMU</u>. In the case where the recommendation is that the <u>APMU</u> should not be approved, the report will identify improvements required in order to be reconsidered for designation as a *WADA* approved <u>APMU</u>. In the case where the recommendation is that the <u>APMU</u> should be approved, the report and recommendation will be submitted to the *WADA* Executive Committee for approval.

7.1.8 Issuing approval letter and publishing APMU list on WADA website

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A letter signed by a duly authorized representative of *WADA* shall be issued in recognition of approval of an <u>APMU</u>. Such letter shall specify the name of the <u>APMU</u> and the period for which the approval is valid. Approval may be granted after the effective date, with retroactive effect. An updated list of approved <u>APMUs</u> shall be published by *WADA* on *WADA*'s website.

7.2 Maintaining WADA Approval

An <u>APMU</u> shall continue to function if the <u>Laboratory's</u> accreditation is suspended, provided that the <u>APMU</u> continues to meet other criteria for approval, and that any non-conformities related to the <u>Suspension</u> of the <u>Laboratory's</u> accreditation do not have an impact on the <u>APMU</u>. The <u>APMU</u>'s approval shall be revoked if the <u>WADA</u> accreditation of the associated <u>Laboratory</u> is revoked.

7.2.1 Minimum number of Passports and APMU Reports

In order to maintain proficiency, *WADA*-approved <u>APMUs</u> are required to review a minimum number of <u>Passports</u> and provide <u>APMU Reports</u> for <u>Passports</u> of <u>Code</u>-compliant <u>Passport Custodians</u> (as determined by <u>WADA</u>). <u>WADA</u> shall monitor the total number of <u>Passports</u> under the responsibility of the <u>APMU</u> and the number of <u>APMU Reports</u> issued by the <u>APMU</u>. If the number falls below 100 haematological <u>Passports</u> or 500 steroidal <u>Passports</u> per year, or the number of <u>APMU Reports</u> for haematological <u>Passports</u> or steroidal <u>Passports</u> falls below 200 or 500, respectively, <u>WADA APMU</u> approval may be suspended or revoked.

7.2.2 Documenting compliance with the WADA APMU Code of Ethics

The <u>APMU</u> shall annually provide to *WADA* a letter of compliance with the provisions of the <u>APMU</u> Code of Ethics (Appendix B), signed by the <u>APMU</u> director. All <u>APMU</u> personnel shall sign the *WADA* <u>APMU</u> Code of Ethics on a yearly basis and the signed documents shall be kept as part of their personnel file. The <u>APMU</u> may be asked to provide documentation of compliance with the provisions of the <u>APMU</u> Code of Ethics.

7.2.3 Documenting sharing of knowledge

The <u>APMU</u> shall proactively share knowledge with other *WADA*-approved <u>APMUs</u>. The <u>APMU</u> should participate at least once annually in a *WADA* working group or an anti-

⁷ Suspension or revocation of <u>APMU</u> approval shall not be considered in decisions on <u>Suspension</u> or <u>Revocation</u> of <u>Laboratory</u> accreditation unless the <u>APMU</u> non-compliance has a clear impact on the function of the <u>Laboratory</u>.

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doping symposium or conference. The <u>APMU</u> shall supply an annual report on sharing of knowledge with *WADA*. A description of this sharing of knowledge is provided in the *WADA* APMU Code of Ethics (Appendix B).

7.2.4 Maintaining professional liability insurance coverage

The <u>APMU</u> shall maintain an ongoing professional liability risk insurance coverage or equivalent which covers the <u>APMU</u> to an amount of no less than 2 million USD annually, and should ensure that the <u>Expert</u> panel has suitable professional liability risk insurance or equivalent coverage. Proof of the corresponding coverage shall be provided to *WADA* upon request.

7.2.5 APMU compliance monitoring by WADA

WADA shall monitor the compliance of <u>APMUs</u> against the requirements listed in applicable *International Standards* and <u>Technical Documents</u>. In addition, *WADA* shall also conduct at least an annual review of <u>APMU</u> compliance and any other relevant information received or collected by *WADA* to assess the overall performance of each <u>APMU</u> and to decide its approval status.

7.2.6 APMU assessment by WADA

WADA reserves the right to conduct document-based audits as well as inspect and assess the <u>APMU</u> through on-site assessments at any time, at <u>WADA</u>'s expense. The notice of an on-site assessment will be made in writing to the <u>APMU</u> director. In exceptional circumstances, the on-site assessment may be unannounced.

7.2.7 Suspension or revocation of approval

Suspension or revocation of <u>APMU</u> approval may occur whenever the <u>APMU</u> fails to comply with applicable *International Standards* and/or <u>Technical Documents</u>, or where such measure is otherwise required in order to protect the interests of the Anti-Doping Community.

Without limitation, the following non-conformities in the routine operations of an <u>APMU</u> may be considered in support of suspension:

- Failure to comply with any of the requirements listed in applicable *International Standards* and/or Technical Documents;
- Failure to cooperate with *WADA* or the relevant <u>Testing Authority</u> in providing documentation;
- Non-compliance(s) with the <u>APMU</u> Code of Ethics;

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- Major changes in key staff without proper and timely notification to WADA;
- Failure to cooperate in any WADA inquiry in relation to the activities of the APMU;
- Non-compliance(s) identified from <u>APMU</u> on-site assessment(s); or
- Loss of resources jeopardizing the quality and/or viability of the APMU.

Non-compliance(s) in <u>APMU</u> performance will be assessed by *WADA* on a case-by-case basis considering the severity and consequences to the anti-doping system. Evidence of serious or multiple non-compliance(s) will be reported by *WADA* to an external assessment panel, who will make a recommendation to *WADA* regarding the approval status of the <u>APMU</u> and the required corrective actions and associated deadlines. *WADA* reserves the right to provisionally suspend an <u>APMU</u>'s approval pending a full investigation. Such a decision may be taken by the Chair of *WADA*'s Executive Committee.

The period and terms of suspension shall be proportionate to the seriousness of the non-compliance(s) and the need to ensure reliable management of *Athlete* <u>Passports</u>. A period of suspension shall be of a duration to be decided by *WADA* and up to a maximum of six (6) months, during which time any non-conformity(ies) must be corrected and such correction documented and reported to *WADA*. If the non-conformity(ies) is/are not corrected during the initial suspension period, the suspension shall either be further extended or the <u>APMU</u> approval revoked. The suspension period may be extended up to a maximum of an additional six (6) months, based on justifiable delays in implementing the satisfactory corrective actions. If the <u>APMU</u> has provided evidence determined to be satisfactory by *WADA* that the non-compliance(s) are corrected, the <u>APMU</u>'s approval shall be re-instated. If the <u>APMU</u> has not provided evidence determined to be satisfactory by *WADA* at the end of the extended suspension period, not to exceed twelve (12) months, the <u>APMU</u>'s approval shall be revoked.

During the period of suspension of the <u>APMU</u>, the management of all *Athlete* <u>Passports</u> shall be transferred by the <u>Passport Custodian</u> to another *WADA*-approved <u>APMU</u>.

The WADA Executive Committee shall revoke the approval of any <u>APMU</u> if it determines that revocation is necessary to ensure reliable management of *Athlete* <u>Passports</u>. Revocation may be based on, but not limited to, the following non-compliances in the routine operations of an <u>APMU</u>:

Repeated suspensions of WADA APMU approval;

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- Systematic failure to comply with applicable *International Standards* and/or Technical Documents;
- Failure to correct a lack of compliance with any of the requirements listed in applicable *International Standards* and/or <u>Technical Documents</u> during a suspension period;
- A serious or repeated violation of the <u>APMU</u> Code of Ethics;
- Repeated and/or continuous failure to cooperate in any WADA inquiry in relation to the activities of the <u>APMU</u>;
- Serious non-compliance(s) identified from <u>APMU</u> on-site assessment(s); or
- Loss of resources jeopardizing the quality and/or viability of the <u>APMU</u>.

7.2.8 Appeals

WADA's decision to suspend or revoke an APMU's approval may be appealed in writing by the APMU before CAS within twenty-one (21) calendar days of the decision notification.

8.0 Passport Management and Administration

The APMU shall manage all Passports under the custody of the Passport Custodian.

8.1 <u>Passport</u> Review Process

The <u>APMU</u> shall carry out the <u>Passport</u> review process as described in Annex L of the ISTI.

8.1.1 When assessing a newly matched Sample in a Passport:

- The <u>APMU</u> shall assess the validity of individual <u>Samples</u> contained within the <u>Passport</u> in <u>ADAMS</u> and address any observed irregularities according to Article 8.2 by updating the <u>APMU Report</u>.
- The <u>APMU</u> shall review any new <u>Samples</u> within the updated <u>Passport</u> and provide <u>Target Testing</u>, <u>Sample</u> analysis or other recommendations via the <u>APMU Report</u> as required.⁸

 $^{^8}$ One of the benefits of the ABP is the ability to focus resources on atypical results requiring attention. As such, it is not mandatory for an $\underline{\mathsf{APMU}}$ to review all newly matched Samples

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- The APMU may request further information from the Passport Custodian including, but not limited to, circumstances and details of Sample collection, transport, and analysis, redacted Athlete competition schedule, history, Athlete performance, redacted Athlete medical information, information on an Adverse Analytical Finding (AAF) that is potentially relevant in the context of the Passport, altitude/whereabouts information which may help them interpret the new Sample.
- If the <u>APMU</u> deems necessary, or upon *ADO* request after reviewing the updated <u>Passport</u>, such as if the <u>APMU</u> identifies suspicious features in the profile, the <u>APMU</u> shall send the <u>Passport</u> to an <u>Expert</u> for review.

8.1.2 When assessing a Passport that generated an ATPF:

- The <u>APMU</u> shall review any previous <u>APMU Reports</u> associated with the <u>Passport</u>.
- The <u>APMU</u> shall assess the validity of individual <u>Samples</u> contained within the <u>Passport</u> in <u>ADAMS</u>, address any irregularities according to Article 8.2 and update the <u>APMU Report</u> accordingly.
- The <u>APMU</u> shall evaluate the need for urgent *Target Testing* of the *Athlete* and communicate *Testing* recommendations to the *ADO* via the <u>APMU</u> <u>Report</u> as required.
- The <u>APMU</u> shall assess the need for additional analysis of existing <u>Samples</u> by specific methods (e.g., Erythropoiesis-Simulating Agents [ESAs], Gas Chromatography Combustion Isotope Ratio Mass Spectrometry [GC/C/IRMS], etc.) and communicate these to the <u>ADO</u> via the <u>APMU Report</u> as required.
- If an <u>Expert</u> has previously recommended that follow-up *Testing* include a minimum number of *Samples* before further review of an *Athlete's* <u>Passport</u> data, the <u>APMU</u> may delay sending the <u>Passport</u> for review until the planned number of *Samples* have been analyzed.
- If, after managing the Sample validity, the <u>Passport</u> remains atypical, the <u>APMU</u> shall, without delay, send the <u>Passport</u> for review in *ADAMS* by an

under their responsibility that do not generate a specific notification requiring mandatory follow-up. Nevertheless, at the discretion of the *ADO*, an <u>APMU</u> may be requested to review normal <u>Passports</u>.

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<u>Expert</u> according to Article L.2.2 of the ISTI. In the event of an <u>Expert</u> opinion of:

- "Likely doping" the <u>APMU</u> shall update the <u>APMU Report</u> indicating "likely doping", specifying any detailed analysis or *Testing* recommendations from the <u>Expert</u> (if provided), and continue the <u>Passport</u> review process according to Article L.3 of the ISTI.
- "Passport suspicious" the <u>APMU</u> shall update the <u>APMU Report</u> indicating "<u>Passport</u> suspicious", highlighting the main atypical features, and outline a <u>Target Testing</u> strategy (if necessary) based on the <u>Expert</u> recommendations, or recommend further analysis (e.g., GC/C/IRMS).
- o "Normal" the <u>APMU</u> shall update the <u>APMU Report</u> indicating "Normal", summarizing the review by the <u>Expert</u> and outlining any *Testing* recommendations provided by the <u>Expert</u>.
- "Likely medical condition" the <u>APMU</u> shall update the <u>APMU</u> Report indicating "Likely medical condition" with submission to additional <u>Experts</u> if recommended in the <u>Expert</u> evaluation, and should inform the <u>Athlete</u> via the <u>ADO</u>.
- 8.1.3 When assessing a *Sample* that generated an *Atypical Passport Finding* <u>Confirmation Procedure</u> Request (*ATPF*-CPR) or a Suspicious Steroid Profile <u>Confirmation Procedure</u> Request (SSP-CPR):
 - The <u>APMU</u> shall assess the validity of the <u>Sample</u> generating the <u>Confirmation Procedure</u> Request in <u>ADAMS</u>, address any irregularities according to Article 8.2 and update the <u>APMU Report</u> accordingly.
 - Where the <u>APMU</u> finds that <u>Confirmation Procedure(s)</u> is/are not necessary according to the Technical Document for Endogenous Anabolic Androgenic Steroids (TDEAAS), the <u>APMU</u> shall update the <u>APMU Report</u> accordingly and notify the <u>Laboratory</u> not to proceed with the <u>Confirmation Procedure(s)</u>.

8.1.4 Expert review of normal Passports

The <u>APMU</u> should provide the <u>Experts</u> from time to time with <u>Passports</u> for review, even when the values are within normal limits and presenting no suspicious elements,

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as this will ensure that <u>Experts</u> are provided a balanced perspective on the *Athletes'* Passports.

8.2 Management of Sample Validity

- 8.2.1 The <u>APMU</u> shall assess and manage the validity of urine and *ABP* blood *Samples* in *ADAMS* according to applicable *International Standards* and <u>Technical Documents</u>, including the International Standard for Laboratories (ISL), the ISTI and the TDEAAS.
- 8.2.2 Any changes in *Sample* validity made by the <u>APMU</u> shall be noted in applicable fields in *ADAMS* and in the <u>APMU Report</u>.
- 8.2.3 Where multiple *Samples* were provided by an *Athlete* during a single <u>Sample</u> <u>Collection Session</u> and are present in a <u>Passport</u>, the <u>APMU</u> shall invalidate all but one *Sample* based on assessment by the <u>APMU</u>.
- 8.2.4 Where multiple *Samples* were provided by an *Athlete* on the same day from different <u>Sample Collection Sessions</u> and are present in a <u>Passport</u>, the <u>APMU</u> may invalidate all but one *Sample* after assessment by the <u>APMU</u> in consultation with the concerned ADO(s).
- 8.2.5 For urine *Samples* where a confounding factor is detected by the <u>Laboratory</u> (*e.g.*, alcohol), the <u>APMU</u> may invalidate the *Sample* when it is considered to affect the sensitivity of the <u>Adaptive Model</u> to detect changes in future *Samples*.
- 8.2.6 For *ABP* blood *Samples* of suspicious profiles where the Blood Stability Score (BSS) could not be calculated, the <u>APMU</u> shall assess the collection-to-analysis time (CAT), any available temperature logger data, and the potential degradation of blood *Markers* in order to evaluate *Sample* validity, liaising with (an) <u>Expert(s)</u> as required.

8.3 The APMU Report

The <u>APMU Report</u> is a central element in the administrative sequence of the <u>ABP</u> that shall be entered and maintained by the <u>APMU</u> in <u>ADAMS</u>. The <u>APMU Report</u> provides an up-to-date overview of the current status of an <u>Athlete's Passport</u> together with recommendations, as appropriate, for efficient follow-up by the <u>Passport Custodian</u>. The <u>APMU Report</u> serves to update the <u>Passport Custodian</u>, <u>WADA</u> and other <u>ADOs</u> with whom the <u>Passport</u> is shared. In addition, it provides a record of events associated with a Passport in <u>ADAMS</u>.

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The <u>APMU Report</u> may include, without limitations:

- Assessments of Sample validity by the <u>APMU</u> and/or <u>Experts</u>;
- Recommendations for complementary <u>Analytical Testing</u> (*e.g.*, ESAs, HIF stabilizers, confirmation of steroid profile, GC/C/IRMS, long-term steroid *Metabolites*, IGF-I, etc.) on *Samples* collected;
- Recommendations for further <u>Analytical Testing</u> on <u>Samples</u> collected previously;
- Recommendations for storing of Samples for extended periods of time for <u>Further Analysis</u>;
- Target Testing recommendations based on available data and <u>Experts'</u> recommendations; and
- A summary of any recent **Expert** reviews.
- 8.3.1 <u>APMU Reports</u> shall be written in English and should use language which maintains the strict anonymity of the *Athlete*.
- 8.3.2 The <u>APMU Report</u> shall not contain any reference to an *AAF* that may be known to the <u>APMU</u>, with the exception of when the *AAF* is used by the <u>APMU</u> as a reason not to perform <u>Confirmation Procedure(s)</u> following an *ATPF*-CPR or SSP-CPR for the steroid profile (see TDEAAS). If the <u>APMU</u> assessment leads to an <u>Expert</u> review, the <u>APMU</u> may, however, separately inform the <u>Expert(s)</u> of the existence of the *AAF*. Depending on the result of the <u>Expert</u> review, the <u>APMU</u> shall further inform the <u>Result Management Authority</u> managing the *AAF* of the result of the <u>Expert</u> review, via the <u>Passport Custodian</u>, if that information is potentially relevant in the context of the result management based on the *AAF*.
- 8.3.3 *Target Testing* recommendations shall be included in the <u>APMU Report</u> with a sufficient level of detail for the <u>Passport Custodian</u> to conduct effective, timely and appropriate *Testing*.

⁹ While <u>Passport</u> sharing is strongly encouraged to enhance *ADO* efficiencies and program effectiveness through exchange of information and mutual recognition of program outcomes, this must be carried out within the framework of the ISPPPI and Article 14.1.4 of the *Code*. The information regarding an *AAF* shall therefore not be recorded in the <u>APMU Report</u> and shall not be disclosed unnecessarily. Only those individuals and/or organizations involved in the applicable results management process should be privy to this information.

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8.4 Compiling the <u>ABP Documentation Package</u>

- 8.4.1 The <u>APMU</u> shall be responsible for compiling the <u>ABP Documentation Package</u> using the template provided by *WADA*. The <u>Passport Custodian</u> shall collect information and bear the cost of compiling <u>ABP Documentation Packages</u> unless it has established an agreement to share the costs with relevant <u>Testing Authorities</u>.
- 8.4.2 Upon request by the <u>APMU</u>, the *ADO* shall provide a detailed *Athlete* competition and altitude schedule, relevant information from *Doping Control* forms, temperature logger and <u>Chain of Custody</u> documentation to the <u>APMU</u>.
- 8.4.3 The <u>APMU</u> shall confer with the <u>Expert</u> panel to determine the scope of such compilation, including the recommended elements and the number of tests that need to be included. It is only mandatory to have a full <u>Laboratory Documentation Package</u> for those tests that are deemed essential by the <u>Expert</u> panel. Other relevant tests, for example those that confirm the baseline levels of a *Marker*, only require a <u>Laboratory</u> Certificate of Analysis. If the <u>Passport Custodian</u> is not the <u>Testing Authority</u> of the test requiring <u>Laboratory</u> documentation, the <u>Passport Custodian</u> shall coordinate with the <u>Testing Authority</u> to obtain such documentation.
- 8.4.4 The following key information shall be included for both Haematological and Steroidal Modules of the <u>ABP Documentation Package</u>:
 - For the *Athlete*: age (excluding the date of birth), gender, and sport/discipline;
 - For all tests: date and time of test, ADAMS ordinal number of the test in the <u>Passport</u>, Sample code number, and biological data and results obtained by the <u>Adaptive Model</u>;
 - For tests selected by the <u>APMU</u> and <u>Expert</u> panel: internal <u>Laboratory</u> (or <u>WADA-Approved Laboratory for the ABP</u>) <u>Sample</u> number, <u>Competition</u> information, <u>Chain of Custody</u> documentation (including <u>Sample</u> collection date and time, and <u>Sample</u> analysis date and time), information from the <u>Doping Control</u> forms for each <u>Sample</u> collected during the period; and
 - A compilation of the latest reviews from the <u>Experts</u> or the joint <u>Expert</u> opinion, as applicable.

For the Haematological Module, the following additional information shall be provided for the tests selected by the <u>APMU</u> and <u>Expert</u> panel:

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- Temperature profile during the transportation of the blood *Sample* and, when available, the BSS;
- <u>Laboratory</u> (or <u>WADA-Approved Laboratory for the ABP</u>) documentation, including blood results, scattergrams, and internal and external quality controls; and
- Answers of the Athlete from the ABP Supplementary Report Form recorded as part of a <u>Sample Collection Session</u>.

For the Steroidal Module, the following additional information shall be provided for the tests selected by the <u>APMU</u> and <u>Expert</u> panel:

- pH of the urine Sample;
- Specific gravity (SG) of the urine Sample;
- <u>Laboratory</u> documentation, including screening and confirmed (when applicable) values of steroid concentrations and ratios;
- GC/C/IRMS results, when applicable;
- Indication of ethanol consumption: urinary concentrations of ethanol and/or ethanol Metabolite(s);
- Indication of microbial growth, including at least 5α-androstandione/A and/or 5β-androstandione/Etio ratio; and
- Information on the presence or absence of confounding factors that may influence the "steroid profile", such as human chorionic gonadotrophin (hCG), ketoconazole, and 5a-reductase inhibitors.

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ABP Expert Code of Conduct Declaration

As an <u>Expert</u> engaged by **[name of the APMU]** to serve as a member of an *Athlete Biological Passport (ABP)* <u>Expert</u> panel, I, the undersigned, _______, affirm and acknowledge that, by signing this declaration, I am bound by the terms of such declaration.

1.0 Passport Review

I shall review all ABP cases in accordance with applicable WADA standards and established scientific knowledge and practices.

I understand that I shall not review <u>Passports</u> from individual *Athletes* on a private basis or from individuals or organizations acting on their behalf outside of standard anti-doping protocols under the World Anti-Doping Code.

2.0 Confidentiality

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

The term "Confidential Information" means all nonpublic information shared throughout my mandate as an *ABP* Expert, information that is identified in writing as CONFIDENTIAL at the time of disclosure or the circumstances surrounding its disclosure, and information that reasonably should be considered as confidential. Confidential Information includes, without limitation (i) nonpublic information relating to technical or non-technical data, algorithms, formulas, patterns, compilations, programs, devices, methods, techniques, drawings, processes, products, services, or lists of actual or potential customers or suppliers which is not commonly known by or available to the public, technology, business plans and methods, promotional and marketing activities, finances and other business affairs, (ii) third-party information that the Disclosing Party is obligated to keep confidential, and (iii) the nature, context and existence of the relationship created by my nomination as an *ABP* Expert, discussion or negotiations between the people involved in this relation. The term "Confidential Information" also includes any modifications or derivatives that contain

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or are based upon such Confidential Information, including analysis, reports or summaries of that information.

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

With the exception of legal obligations, authorisation by virtue of my office, the order of a court or law enforcement agency of competent jurisdiction, or the express authorisation of **[person in charge of the organization]**, I shall not reveal or hand over to anybody, particularly to representatives of the media, any confidential information or document that is brought to my attention or is in my possession, either directly or indirectly through my participation as a member of an *ABP* <u>Expert</u> panel of **[name of the organization]**, excluding information that has already been made public or is in my possession independently of **[name of the organization]**. I shall not use my title as member of an *ABP* <u>Expert</u> panel for any public declaration.

Furthermore, I understand that the violation of my confidentiality obligation as described herein may result in possible legal proceedings against me and the immediate termination of my participation as a member of an *ABP* Expert panel of [name of the organization].

3.0 Conflicts of Interest

In the event of any conflict of interest with a party to the evaluation for an *Athlete's* <u>Passport</u> that an *ABP* <u>Expert</u> panel of **[name of the organization]** may have to handle, I shall immediately inform **[person in charge of the organization]** and abstain from taking part in the decision procedure for the specific case in question.

4.0 Conduct Detrimental to the Anti-Doping Program

I shall not engage in conduct or activities that undermine or are detrimental to the anti-doping programs of WADA, an International Federation, a National Anti-Doping Organization, a National Olympic Committee, a Regional Anti-Doping Organization, a Major Event Organization, or the International Olympic Committee or International Paralympic Committee. Such conduct could include, but is not limited to, conviction

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for fraud, embezzlement, perjury, etc., or knowledge of such, that would cast doubt on the integrity of the relevant anti-doping program(s).

I shall not provide counsel, advice or information to *Athletes* or other *Persons* regarding techniques or methods that may mask the detection of, alter the metabolism of, or suppress the excretion of a *Prohibited Substance* or *Marker(s)* of a *Prohibited Substance* or *Prohibited Method*.

Outside the context of an arbitration hearing, I shall not provide information to an *Athlete* or *Athlete Support Personnel* or any other *Person* about a testing method that might assist the *Athlete* in avoiding detection of the *Use* of a *Prohibited Substance* or *Prohibited Method*. I shall not assist an *Athlete* in avoiding collection of a representative *Sample* (*e.g.*, advice on masking or detection windows). This paragraph does not prohibit presentations to educate *Athletes*, students, or others concerning anti-doping programs.

If I am requested by any party or a tribunal or court of competent jurisdiction to appear as an expert witness, I understand that I am expected to provide an independent, scientifically valid expert testimony.

I shall not issue (publish) any public warning statements related to findings observed during <u>Passport</u> reviews. The responsibility for evaluation of these findings with further action and publication, if considered necessary, shall be left to the relevant *Anti-Doping Organization(s)*.

5.0 Declaration

By signing this declaration, I declare that I will abide by the Code of Conduct as described, and that my failure to abide by the Code of Conduct will result in the immediate termination of my participation as a member of an *ABP* Expert panel of [name of the organization], in addition to any disciplinary sanctions that could be imposed against me by a disciplinary panel of competent jurisdiction.

DATED THE	DAY OF	, 2	20
BY			
		(SIGNATURE)	

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Athlete Passport Management Unit Code of Ethics

1.0 Confidentiality

The nature of the responsibilities of the <u>Athlete Passport Management Unit (APMU)</u> is such that the <u>APMU</u> shall come into contact with or be made aware of sensitive and Confidential Information.

The term "Confidential Information" means all non-public information shared throughout the mandate of the APMU, information that is identified in writing as CONFIDENTIAL at the time of disclosure or the circumstances surrounding its disclosure, and information that reasonably should be considered as confidential. Confidential Information includes, without limitation (i) non-public information relating to technical or non-technical data, algorithms, formulas, patterns, compilations, programs, devices, methods, techniques, drawings, processes, products, services, or lists of actual or potential customers or suppliers which is not commonly known by or available to the public, technology, business plans and methods, promotional and marketing activities, finances and other business affairs, (ii) third-party information that the Disclosing Party is obligated to keep confidential, and (iii) discussion or negotiations between the relevant people involved. The term "Confidential Information" also includes any modifications or derivatives that contain or are based upon such Confidential Information, including analysis, reports or summaries of that information.

<u>APMUs</u> shall respect all of the requirements relating to the confidentiality of the information obtained in any way whatsoever during the course of their activities throughout and beyond the period of <u>APMU</u> approval by *WADA*.

With the exception of legal obligations, authorization by the <u>Passport Custodian</u>, or the order of a court or law enforcement agency of competent jurisdiction, an <u>APMU</u> shall not reveal or hand over to anybody, particularly to representatives of the media, any confidential information or document that is obtained, either directly or indirectly through its activities, excluding information that has already been made public or is its possession independently of the <u>Passport Custodian</u>. The director of the <u>APMU</u>, their delegates and <u>APMU</u> personnel shall not discuss or make any comment to the media on individual Passports or results without the express consent of the

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organization that is asserting the *Adverse Passport Finding (APF)* in adjudication (i.e., the <u>Passport Custodian</u> or *WADA*).

2.0 Passport Management

<u>APMUs</u> shall manage <u>Passports</u> in the <u>Anti-Doping Administration and Management System (ADAMS)</u> on behalf of the <u>Passport Custodian</u> in accordance with the requirements of the TDAPMU, Annex L of the International Standard for Testing and Investigations (ISTI), and other applicable <u>International Standards</u> and <u>Technical Documents</u>.

<u>APMUs</u> shall not manage or review <u>Passports</u> from individual *Athletes* on a private basis or from individuals or organizations acting on their behalf.

The <u>APMU</u> shall not provide services in a *Doping Control* adjudication, unless specifically requested by the responsible <u>Passport Custodian</u>, *WADA*, or a Hearing Body.

3.0 Sharing of Knowledge

When the <u>APMU</u> identifies a pattern in a <u>Passport</u> that may be attributed to the *Use* of a new form of *Prohibited Substance* or *Prohibited Method*, the <u>APMU</u> shall share such information with *WADA* within sixty (60) days.

Sharing of knowledge can occur by participation in scientific meetings, publication of results of research, or sharing of specific details of <u>Passport</u> management, such as *Target Testing* strategies, approaches to managing sample validity, information regarding confounding factors, or special analyses necessary for detection. The <u>APMU</u> director and staff shall participate in developing standards for best practice and enhancing uniformity of Passport management in the *WADA* approved APMU system.

4.0 Conduct Detrimental to the Anti-Doping Program

The <u>APMU</u> personnel shall not engage in conduct or activities that undermine or are detrimental to the World Anti-doping Program¹. Such conduct could include, but is

¹ The World Anti-doping Program comprises the anti-doping programs of *WADA* and all *Code Signatories*, including International Federations, *National Anti-Doping Organizations*, *Regional*

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not limited to, fraud, embezzlement, perjury, etc., or knowledge of such, that would cast doubt on the integrity of the anti-doping program.

No <u>APMU</u> personnel shall provide counsel, advice or information to *Athletes* or others regarding techniques or methods used to mask or avoid detection of, alter metabolism of, or suppress excretion of a *Prohibited Substance* or *Marker(s)* of the *Use* of a *Prohibited Substance* or *Prohibited Method*.

Outside of information provided in the context of anti-doping proceedings, no <u>APMU</u> personnel shall provide information about *Marker(s)* of the *ABP* which could be used to avoid the detection of doping, to an *Athlete* or *Athlete Support Personnel*. No <u>APMU</u> staff shall assist an *Athlete* in avoiding collection of a representative *Sample* (*e.g.*, advice on masking strategies or detection windows). This paragraph does not prohibit general presentations to educate *Athletes*, students, or others concerning anti-doping programs and *Prohibited Substances* or *Prohibited Methods*. Such provisions shall remain valid for a minimum of five (5) years following termination of the contractual relationship of any employee to an <u>APMU</u>.

If an <u>APMU</u> staff is requested to provide evidence in anti-doping proceedings, they are expected to provide independent, scientifically-valid expert testimony.

The <u>APMU</u> shall not issue (publish) any public warning statements related to the <u>Passport</u> findings. The responsibility for publication of these findings, if considered necessary, shall be left to a political decision-making body (e.g., *Anti-Doping Organization*, International Federation or *WADA*).

5.0 Breach and Enforceability

A failure to respect any of the provisions of this Code of Ethics may result in the <u>APMU</u> being subject to disciplinary proceedings instituted by *WADA* to either suspend or revoke its <u>APMU</u> approval in accordance with Article 7.2.7 of the TDAPMU. In addition, a failure to respect any of the provisions of this Code of Ethics may result in <u>APMU</u> staff being subject to disciplinary action by the <u>APMU</u>, resulting in consequences beyond those stipulated under the TDAPMU, including potential termination of employment or, where applicable, the imposition of criminal charges.

Anti-Doping Organizations, Major Event Organizations, the International Olympic Committee or the International Paralympic Committee.