Checklist for Therapeutic Use Exemption (TUE) Application:

Growth Hormone Deficiency – Child, Adolescent and Adult

Prohibited Substance: Human Growth Hormone

This Checklist is to guide the athlete and their physician on the requirements for a TUE application that will allow the TUE Committee to assess whether the relevant International Standard for Therapeutic Exemptions (ISTUE) criteria are met.

Please note that the completed TUE application form alone is not sufficient; supporting documents MUST be provided. A completed application and checklist do NOT guarantee the granting of a TUE. Conversely, in some situations a legitimate application may not include every element on the checklist.

☐	**TUE Application form** must include:	
	☐	All sections completed legibly
	☐	All information submitted in [language(s) as per ADO preferences]
	☐	A signature from the applying physician
	☐	The Athlete's signature
☐	**Medical report** should include details of:	
	☐	Medical history: Genetic or acquired causes of hypothalamic-pituitary disease (e.g., pituitary tumor; irradiation, surgery, traumatic brain injury), presence of other pituitary hormone deficiencies and information supporting a diagnosis of growth hormone deficiency (GHD): • Adult[i]: Fatigue, poor exercise capacity, abdominal obesity, impaired psychosocial function • Transition[ii]: Childhood short stature and growth deceleration; childhood human growth hormone (hGH) therapy
	☐	Physical exam: Clinical evidence of adult GHD such as central adiposity, pale complexion, thin dry skin, sparse body hairs and for the patient in transition, evidence of developmental or somatic immaturity.
☐	**Diagnostic test results** should include copies of:	
	☐	Laboratory tests (with reference ranges): Insulin-like growth factor-1 (IGF-1) measured after 2 – 4 weeks off hGH in those on therapy; no earlier than 12 months after brain injury in those with post-traumatic etiology. Baseline pituitary function: thyroid-stimulating hormone (TSH), follicle-stimulating hormone (FSH), luteinizing hormone (LH), prolactin. Morning cortisol as a reliable indicator of adrenocorticotropic hormone (ACTH) status. MRI of pituitary/hypothalamus to assess structural abnormalities for all new onset GHD (any age) unless of genetic cause (see below).
	☐	If diagnosed during childhood, gene (GH-1 or GHRH-R) or transcription factor mutations (e.g., PROP-1, POU1F1 (Pit-1)) known to result in hypopituitarism.
	☐	Growth hormone stimulation tests employing in: • Adults: Insulin tolerance test, glucagon stimulation test, growth hormone–releasing hormone (GHRH)-arginine stimulation test, macimorelin test. • Transition: Insulin tolerance test, glucagon stimulation test, macimorelin test. Note: Stimulation tests are not required when hypopituitarism is diagnosed (≥3 other pituitary hormone deficits or gene or transcription factor mutations present (see above). Additional tests are also not required if IGF-1 levels 2 – 4 weeks after stopping treatment remain below -2 SD.

[i] Adult-onset deficiency
[ii] Transition from childhood, i.e. when linear growth has ceased.