Standard Teratoma Guidance 1.0

1 Definitions

1.1 teratoma A type of germ cell tumor that may contain several different types of tissue and sometimes mature elements such as hair, muscle, and bone.

2 Description of standard teratoma research:

2.1 What qualifies as standard teratoma research?

2.1.1 General description. Injection will only occur at standard sites and the application should list those sites

2.1.2 Examples of standard sites:

- Non-surgical: subcutaneous (base of the neck -between the shoulder blades),
- intramuscular (hindleg)
- Surgical: kidney capsule, testis capsule

2.1.3 Examples of standard applications:

- To determine the ability of pluripotent stem cells that contribute to the meso-, endo- and ectodermal lineages and contribute to a specific tissue type normally present in early development, determine the relative maturity of the tissues within the teratoma.
- The PI will describe methods to ensure that no injected animals will be bred.
- The application will describe a limited length of time that the animal will survive before the teratoma assay is completed.

3 Addition of cell sources and respective provenance documentation

3.1 The Initial application should document intended research whereas the annual survey and renewal should describe what lines were used.

3.2 The PI will be responsible for submitting an ESCRO amendment form to report any proposed addition of cell sources and their respective provenance documentation.

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3.3 The type of review for adding proposed cell sources and their respective provenance documentation will be eligible for minimal review but will be made at the discretion of the ESCRO Chair.

4 Disclosure of unusual and unanticipated occurrences:

4.1 It is the responsibility of the Principal Investigator to inform ESCRO of any unusual occurrences outside the expected range of events by no later than 10 business days after discovery of the result. Examples of unusual events that require ESCRO notification include: if a human embryo develops or if the transplanted cells migrate to other sites outside of the targeted teratoma site.