Reporting of Serious Adverse Events and Reactions (SAEARs) is mandatory for Tissue Establishments (NuVision Biotherapies Ltd or *NuVision*) under the Human Tissue Authority (HTA) Guide to Quality and Safety Assurance for Human Tissue and Cells for Patient Treatment and the Human Tissue (Quality and Safety for Human Application) Regulations. In order to accurately report serious adverse events and reactions it is critical that all Tereo® processed human tissue products are fully traceable from the donor to recipient/disposal and vice versa. The requirements for the maintenance of traceability and reporting serious adverse events or reactions are prescribed in the Tissue Supply Agreement (TSA) between NuVision and its Customers.

In the event of a Serious Adverse Event or Reaction, please report this to NuVision without delay within 24 hours via our monitored email incident@nu-vision.co.uk or by telephoning 0115 784 0120. Please also complete and return the fields in the form below. Other Quality incidents (which may not classify as either SAE or SAR) may also be reported.

Type of event (please indicate by ticking appropriate box):

- ☐ **Serious Adverse Event (SAE)** - *any untoward occurrence that might lead to the transmission of a communicable disease, to death or life-threatening, disabling, or incapacitating conditions for patients or which might result in, or prolong, hospitalisation or morbidity.*
- ☐ **Serious Adverse Reaction (SAR)** - *an unintended response, including a communicable disease, in the recipient associated with the procurement or human application of tissues and cells that is fatal, life threatening, disabling, incapacitating or which results in, or prolongs, hospitalisation or morbidity.*
- ☐ **Quality Incident** – *any element related to the product in use (e.g., transport, packaging, labelling) that may potentially affect or include aspects such as product quality, patient safety.*

Details of Event:	

Contact details (please complete details for the referring professional):

Name:	**Title & Position:**
Hospital:	**Telephone number (direct line):**
Email address:	
Date:	**Signature:**

Procedure & Product Details:

Procedure description:	**Procedure/event date:**
Number of Products involved:	**Labels if available:**
Single European Code(s) (SEC) or Unique Identifying Code (UIC):	

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Report received by:	**How (e-mail, phone):**	**Date & time:**
Actioned by:	**Reportable to HTA:** ☐ **No** ☐ **Yes**	**Date & time Reported to HTA:**
Case Ref #:	**Further action:**	

Approval & Review History Page

1. Document Approval

Authored by	Name: Joe Brown	Function: Quality Technician	Signature: 	Date (yyyy-mm-dd): 2023-10-05
Approved by	**Name:** Beverley Lancashire-Hunter	**Function:** Quality Manager	**Signature:** 	**Date:** 2023-10-05

2. Review History

Version No	Issue Date (yyyy-mm-dd):	Reason for Change	Author
04	2022-11-02	Updated to align with issue date of SOP. Transferred to new form template.	Adrian Del Arenal, Operations Manager (DI)
05	2023-03-20	Updated to align with issue date of SOP.	Adrian Del Arenal, Operations Manager (DI)
06	2023-10-05	Addition of Unique Identifying Code (UIC)	Joe Brown, Quality Technician