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 Incident:	*Provide full details of the incident in this section including; the date the patient was treated, reason for patient treatment, product(s) used in treatment, history/timeline of the incident when is started and any actions taken to resolve the incident and any other information to aid the incident investigation.*

Product Details:

Record Product Name: *e.g., Omnigen C and OmniLenz C*
Omnigen - Record the Unique Identifying Code (UIC) or Single European Code(s) (SEC):
OmniLenz – Record the LOT/Serial Number: *(N/A if not used)*
Please affix Omnigen label(s) in this section if available:

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

Name:	**Title:**
Hospital/Optician Branch:	**Telephone number (direct line):**
Email address:	
Date:	**Signature:**

FOR NUVISION USE ONLY

Report received by:
How (e-mail, phone):
Date & time:
Actioned by:
NuVision SAER Reference:
Reported to HTA: *Circle as appropriate* **YES** **NO** **Reported by (Print Name):** **Signature:**
Date and Time Reported to HTA:
Case Ref #:
Record full details of the incident investigation and outcomes, actions taken. Ensure any email corresponsdance is filed with the completed incident form.:

Approval & Review History Page

1. Document Approval

Authored by	Name:	Function:	Signature:	Date (yyyy-mm-dd):
	Kerey Holton	Quality Technican		2025-04-10
Approved by	**Name:**	**Function:**	**Signature:**	**Date:**
	Beverley Lancashire-Hunter	Quality Manager		2025-04-10

2. Review History

Version No	Issue Date (yyyy-mm-dd):	Reason for Change	Author
06	2023-10-05	Addition of Unique Identifying Code (UIC).	Joe Brown, Quality Technician
07	2024-05-09	Updated to align with issue date of SOP.	Kerey Holton, Quality Technician
08	2025-04-10	Reformatted form.	Kerey Holton, Quality Technician