	Title: Incident Report Form		Issue date: 2026-06-08
	Ref: D-Q12a	Version: 10	


Reporting of Serious Adverse Events and Reactions (SAERs) is mandatory for Tissue Establishments (NuVision Biotherapies Ltd) 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 SAERs it is critical that all Omnigen products are fully traceable to the recipient. The requirements for the maintenance of traceability and reporting SAERs 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
<p>Provide full details of the incident in this section including the following:</p> <ul style="list-style-type: none"> • Date patient was initially treated and date of followup • Reason patient was treated • Existing preconditions • Product(s) used in patient treatment • History/timeline of the incident when it started and any actions taken to resolve the incident including medication and follow-up assessments • Any other information relevant to the incident

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Omnigen Details	
Omnigen product used e.g., Omnigen C	Unique Identifying Code (UIC) or Single European Code (SEC)
Affix the Omnigen label below if available (label found on cardboard envelope):	
e.g. <div style="border: 1px solid black; padding: 5px; margin: 10px 0;">  </div>	
OmniLenz Details (please record N/A below if OmniLenz not used)	
OmniLenz product used e.g., OmniLenz C	OmniLenz LOT/serial number
Omnigen Kit Details	
Omnigen Kit used e.g., Omnigen Kit C, L or View+	Omnigen Kit Serial Number


Contact details for the referring professional:

Name (including title):	
Hospital/Optician Branch:	
Email Address:	
Telephone Number:	
Signature and Date:	

For NuVision use only:

Report received by:	
How (e-mail, phone):	
Date & time:	
Actioned by:	
NuVision SAER Reference:	
Reported to HTA/MHRA:	
Reported by:	
Date and Time Reported to HTA/MHRA:	
Ref Number:	

Record full details of the incident investigation and outcomes, actions taken. Ensure any email correspondance is filed with the completed incident form.

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Approval & Review History Page

1. Document Approval

Authored by	Name: Kerey Holton	Function: Quality Technican	Signature:	Date (yyyy-mm-dd): 2026-06-08
Approved by	Name: Beverley Lancashire-Hunter	Function: Quality Manager	Signature:	Date: 2026-06-08

2. Review History

Version No	Issue Date (yyyy-mm-dd):	Reason for Change	Author
08	2025-04-10	Reformatted form.	Kerey Holton, Quality Technician
09	2026-02-24	Reformatted form.	Joe Brown, Quality Technician
10	2026-06-08	Updated form to include the Omnigen Kit and reference to the MHRA.	Kerey Holton, Quality Technician