Incident Report Form (SAEARS) – Omnigen (IRF-1)

Responsibilities of the Tissue Establishment
It is a mandatory requirement under the European Union Tissues and Cells Directive (EUCTD) for tissue establishments to report any serious adverse events/reactions (SAEARs) with a tissue back to the distributor. This responsibility, together with the need for the tissue establishment to maintain traceability of the tissue to recipient or disposal, forms part of the End User Agreement (EUA) between NuVision Biotherapies (NuVision) and our customers (the Tissue Establishment).

In the event of a Serious Adverse Event/Reaction, please report this to NuVision within 24 hours via our monitored email info@nu-vision.co.uk or by telephoning 0115 784 0120. Please also complete and return the fields in the form below. Quality Incident reports may also be submitted.

Please complete fully and legibly using black ink:

1. **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 that may potentially affect or include aspects such as: product quality, patient safety.*

2. **Details of event (please describe in the space below):**

_____
_____
_____
_____
_____

3. **Contact details (please complete details for the referring professional):**

Name:_____
Title & Position:_____
Hospital:_____
Contact Telephone Number (direct line):_____
Email address:_____
Date:_____Signature:_____

4. **Procedure & Product Details:**

Procedure Type:_____ Procedure Date:_____
Omnigen: Quantity Used _____
Unit Numbers: _____
_____
_____

_____

FOR INTERNAL USE ONLY
Report Received by: _____ Date & Time:_____
Actioned by: _____ Case Ref #:_____