RISK ASSESSMENT REVIEW/REVISION RECORD

Risk Assessment Ref No:	CBE/BRA/158 CBE/GMO/158	Version Number 6

This risk assessment should be reviewed **annually** or more frequently if there is any change in the work, or if new information becomes available that indicates the assessment may no longer be valid. **This form should be attached to the front of the current version of the risk assessment or to the new version of the risk assessment if one is issued**

The following review has been carried out on the dates indicated and either the assessment remains valid or it has been amended as indicated.	
Name(s) of reviewer: Angharad Elizabeth Evans	Date:30/01/2020
Signature:	
Reason for Review: Will be transfecting HEK293 / HEK293T cells to produce Lentivirus with Plasmids purchased from Sigma	
Revision Required (Y/N)	**Y**

If Yes, give details of the revision:

The process and methodology will be exactly the same as what is currently undertaken, just with different plasmids used to produce the lentiviral vectors.

The packaging mix and plasmid used are both commercially available by Sigma. The plasmid used will be a lentivirus vector that contains a gene encoding TurboGFP™ and is driven by the CMV promoter. The plasmid (MISSION pLKO.1-puro-CMV-TurboGFP Positive Control Plasmid DNA) (product code: SHC003) contains TurboGFP, which an improved variant of the green fluorescent protein copGFP cloned from *Pontellina plumata.*

In addition to this plasmid, a 3rd generation lentivirus packaging mix (MISSION Lentiviral Packaging Mix), containing an optimised set of packaging plasmids, will also be sourced from Sigma (SHP001). This packaging mix is designed to be co-transfected into both HEK293 and HEK293T cells.

The plasmids used are not being genetically modified themselves, they are simply a vehicle that

allow the production and expansion of lentiviral vectors in host HEK293 / HEK293T cells. With regards to safety, the NIH states that the major risks to be considered for research with HIV-1 based lentiviral vectors are the potential for generation of replication-competent lentivirus (RCL), and the potential for oncogenesis. Both risks can and will be mitigated by the safety features and nature of the vector and also exacerbated by the nature of the transgene insert encoded by the vector.

Approval:

Instructions for Reviewer:

1. *The completed form should be forwarded to the CBE Quality Manager. NOTE: Significant revision (See Guidelines GN006 & GN007) will require approval by the person supervising the work and subsequent review and approval by the original approving authority. This may require a revised version of the risk assessment to be issued for re-approval.*
2. *Where an annual review concludes that the risk assessment is still valid ie no revision is required, this should be recorded and the completed form forwarded to the CBE Quality Manager.*

Name of Approver:	Date: 30/1/20.
Position: LAB MANAGER	
Signature: K. Shed	
Name of Approver:	Date:
Position:	
Signature:	
Name of Approver:	Date:
Position:	
Signature:	
Name of Approver:	Date:

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