

Centre for Biological Engineering		
Document Ref: FSOP048	Issue no v3.1	Issue Date 18-Dec-12

RISK ASSESSMENT REVIEW/REVISION RECORD

Risk Assessment Ref No:	CBE/BRA/10	Version Number
		2

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: Jon Harriman	Date: 12/08/2019
Signature:	
Reason for Review: Addition of Technician Jon Harriman to CBE/BRA/10 from 01/09/2019 for culture of hematopoietic stem cells (CD34+). New avenue of CD34+ culture in G-Rex silicone membrane flask format.	
Revision Required (Y/N)	Y
If Yes, give details of the revision: G-Rex flasks comprise of a sealed unit containing a silicone gas permeable membrane for cell growth in a layer and a headspace of culture medium. G-Rex flasks are manipulated in the BSC and incubated in the same way as standard cell culture plastic ware i.e. T-flasks. Cryopreserved 5E6 CD34+ cells (from mobilised peripheral blood) will be purchased from a commercial supplier and cultured at 5E5/mL in 20mL of medium per flask. Cells will be expanded to 1.5E6 cells/mL over a 15-day culture period. This protocol consists of standard CD34+ cell culture methods, reagents, equipment and in typical cell concentrations and working volumes. Therefore, any risks are already assessed in CBE/BRA/10. The risk profile for CBE/BRA/10 does not change with this review. Jon will be supervised by Dr. Katie Glen (added to BRA 31/03/2011) where required although Jon has previous experience with CD34+ culture under other BRAs including required equipment e.g. CBE/BRA/165.	

Issued by: P.Hourd	Authorised by: R.I.Temple <i>R.I. Temple</i>	Page 1 of 2
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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: <i>Katie Glen</i>	Date: <i>11/9/19</i>
Position: <i>RA</i>	
Signature: 	
Name of Approver: <i>Rob Thomas</i>	Date: <i>11/9/19</i>
Position: <i>PI</i>	
Signature: 	
Name of Approver: <i>KULVINDAR SIKAND</i>	Date: <i>11/9/19</i>
Position: <i>QUALITY MANAGER</i>	
Signature: 	
Name of Approver:	Date:
Position:	
Signature:	