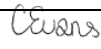
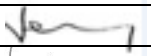
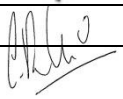
Work Instruction	**The process of reviewing Safety Documents for the Ensemble Clinical Trial**
Clinical Trial No.	MA30143
Version	V1.0
Date	05 Feb 2020

1.0	**Process & Objectives**
	This instruction describes the processes that are required to access and download safety reports from the Roche CTSP. This applies to the Ensemble clinical trial of which University Hospitals Plymouth is a participating site.
2.0	**Personnel & Responsibilities**
	Research Nurse – - Accessing CTSP, downloading and printing of safety documents. - Providing safety documents to the P.I - Storing of documents within the Investigator Site File. **Clinical Trial Co-ordinator** – - Accessing CTSP and downloading and printing of safety documents. - Providing safety documents to the P.I. **Principal Investigator** – - P.I oversight. - Signing to confirm receipt of safety documents.
3.0	**Timeline Requirements**
	During the course of the trial, safety document review is required every 6 months. Reports should be accessed and signed off within one week of receiving an alert notification.
4.0	**Procedure**
	Notification of report alert - An alert will be received via e-mail to inform personnel that a report is available to be reviewed. **Providing report to the Principal Investigator** - Reports will be downloaded, printed and provided to the P.I to be reviewed within one week of receiving an alert notification. **Signing of Reports** - Reports will be signed and dated by the Principal Investigator. - Once reports are signed they will be returned to the research nurse for filing.
5.0	**Document Storage**
	- Signed documents will be stored within the Ensemble Investigator Site File, located in University Hospitals Plymouth.
6.0	**Training Requirements**
	- All personnel will have completed Ensemble study specific training and will have signed the delegation log. - This task will be added to the delegation log as **other-safety document management.*

Name	**Signature**	**Title**	**Date**
Author			
Charley Evans		Clinical Trial Coordinator	07 Feb 2020
Reviewer			
Jeremy Hobart		Principal Investigator	07 Feb 2020
Chris Rollinson		Research Governance Manager	13 Feb 2020