Barts and The London
School of Medicine and Dentistry

| Standard Operating Procedures (SOP) for: **WAIT Trial QA/QC** | | | |
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| SOP Number: | **12** | Version Number: | **1** |
| Effective Date: | | Review Date: | |

| Author: | **Iain Dickson** |
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| Authorisation: | |
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| Name / Position | **Dr Tom Vulliamy** |
| Signature | |
| Date | |

| Purpose and Objective: |
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| To document quality assurance/quality control (QA/QC) procedures taking place within the WAIT trial. |

| SOP Text |
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| | Responsibility | Activity |
|---|---|---|
| 1. | Lab Technician | **Sample Receipt –** When a sample arrives, it is checked over for packaging, labelling and for any leaks. This is documented for each sample in the 'WAIT Sample Receipt' log, kept in filing cabinet GWHD-6, in the paediatric write-up area. |
| 2. | Lab Technician | **Sample Processing –** All samples are amplified in duplicate. All samples are also run alongside positive standards. Three of these standards were used to validate the method (see 'Method Validation' in the WAIT trial lab site file) and were sequenced to confirm their genotype. They are as follows:<br>S1-W001– 5/5 genotype<br>S2-2535 – 4/5 genotype<br>S3-2551 – 3/5 genotype<br>A fourth standard with the 5/6 genotype is also run with all samples. This standard originated from a trial sample which was found to have the 5/6 genotype. DNA from this saliva sample was re-extracted and is labelled with the same trial number followed by a (2), e.g. LO-140(2). As a standard, it will therefore appear on the genotyping worksheet as, for example, S4-LO140(2). |
| 3. | Lab Technician | **Repeat Testing –** When there is a low number of samples to be analysed and space on the genotyping plate, randomly picked old trial samples are re-amplified and re-genotyped. This is demonstrated on the genotyping worksheet by 'QA/QC' in the margins next to the samples being re-run. Periodically, a whole 'QA/QC' run may take place where all the samples on the plate are re-genotyped. This again will denoted by 'QA/QC' on the worksheet. |
| 4. | Lab Technician | **Results Reporting –** All results in the WAIT trial are double checked by another member of the lab staff, Dr. Tom Vulliamy. Before a report or sample result is sent out, Dr. Vulliamy will look over the raw data and double check the genotype result, as well as the stratification. Please see the 'Results Reporting SOP', |