## Objective

To ensure the donation process is not lengthened when H&I/Virology laboratories are unable to process donor bloods. The document provides NHS laboratories, Hub Operations and Specialist Nurse a single process to ensure H&I/Virology laboratory closures are communicated and managed appropriately.

### Changes in this version

"SNOD" changed to "SN" throughout the document and definition for "SN" added and RM changed to RHoN

## Roles

**Laboratories**

- Report instances whereby they are unable to process donor bloods.
- Report when their laboratory is fully functional.
- Notify back up laboratory (short term closure only)
- Notify SN if the blood samples have already been sent (see section 11)

**Hub Operations**

- Inform Organ Donation Services Teams and Quality Assurance of H&I/Virology laboratory closures and re-opening.

**Quality Assurance**

- Monitor prolonged laboratory closure.
- Liaise with operational staff to record the laboratory closure and document the risks.

**Commissioning**

- To monitor instances of laboratory disruption
- To work with other stakeholders to monitor long term closures
- To lead Stakeholder meetings for long term closures.

**Specialist Nurse**

- Arrange transport of samples to back-up laboratory where appropriate (see section 11)

# Instructions

## Laboratory

## 1. Inform Hub Operations of the laboratory closure.

1.1 Email Hub Operations immediately when aware of a laboratory service disruption, including known periods of planned downtime.

- Email: odthub.operations@nhsbt.nhs.uk
- Email title must be: OPERATIONAL DISRUPTION AT LABORATORY
- The email must detail what the disruption is and how long it is expected to last.

1.2 Follow the email up with a telephone call to Hub Operations.

- Call: 01179 757580

1.3 Notify 1st Back Up Laboratory in the event of unplanned/short term closure. See **INF1583** - Back Up Laboratories for Deceased Donor Virology Testing, and INF1466 – Back Up Laboratories for Deceased Donor Tissue Typing Testing.

**IF THE LABORATORY HAS RECEIVED THE BLOOD SAMPLE, PLEASE REFER TO SECTION 11**

## Hub Operations

# 2. Inform key stakeholders of the laboratory closure.

2.1 Attach the email sent by the lab to a template email called “laboratory disruption”.

- The “laboratory disruption” template is stored in the “fax and email templates” in shared F drive.
- This template email has been prepopulated with SNs, RHoN, Commissioning, and QA team contacts. It is titled “LABORATORY DISRUPTION” and informs SNs to review **INF1466 for H&I and INF1583 for Virology** for further information on where to send bloods during an outage.

2.2 Forward the email with high importance to all SNs, RHoN, Commissioning Team and Quality Assurance.

2.3 If out of hours, notify the RHoN On-Call via a telephone call.

→ **IF THE CLOSURE IS UNPLANNED/SHORT TERM go to Step 3**

→ **IF THE CLOSURE IS PLANNED/LONG TERM go to Step 4**

## Quality Assurance

# 3. Assess whether a change control is required

→ **IF A CHANGE CONTROL IS REQUIRED, go to Step 4**

→ **IF A CHANGE CONTROL IS NOT REQUIRED, go to Step 7**

# 4. Document and assess the risk of the laboratory closure

4.1 Raise a change control to record the laboratory closure. Change control detail should begin ‘ODT - Laboratory Closure’ and include:

- Laboratory name
- Contingency laboratory
- Anticipated closure timeframe
- Closure reason

4.2 Utilise **FRM4889** to record the risk.

4.3 Liaise with relevant operational staff (Regional/Team Managers) to document and assess the risk.

4.4 Save a copy of the laboratory closure email in the QPulse record.

4.5 Add an action for QA to follow up with the Commissioning Team up to one working day before the anticipated resumption of service.

**Commissioning Team**

## 5. Stakeholder Review

5.1 Commissioning team to arrange a meeting to discuss alternative arrangements.

5.2 For long term closures, review donor hospital allocations and impact of activity on back-up laboratories

5.3 NHSBT Senior Commissioning Manager to contact other laboratories regarding increases in their activity and confirm they can facilitate this in writing. Record arrangements in QPulse under the open change control.

5.4 Contact the disrupted laboratory up to one working day before the anticipated resumption to confirm they will be resuming normal service. Laboratory contact details can be found in the Donor Handbooks.

**Laboratory**

## 6. Inform Hub Operations of the resumption of their laboratory service.

6.1 Email Hub Operations when the laboratory service has resumed. - Email: odthub.operations@nhsbt.nhs.uk Email title must be: OPERATIONAL DISRUPTION AT LABORATORY RESOLVED

6.2 Follow the email up by a telephone call to Hub Operations. - Call: 01179 757580

**Hub Operations**

## 7. Inform SNs, Commissioning and QA of the resumption in laboratory service.

7.1 Forward the email to all SNs, RHoN, Commissioning Team and Quality Assurance. Title the forwarded email OPERATIONAL DISRUPTION AT LABORATORY RESOLVED.

**Commissioning Team**

## 8. Review closure information.

8.1 Notify in writing to back-up laboratories that samples will revert to original arrangements.

**Quality Assurance**

## 9. Review closure information.

9.1 Receive and review closure information.

## 10. Manage the QPulse record.

10.1 Upload a copy of the email forwarded by Hub Operations stating the laboratory has re-opened.

10.2 When all QPulse actions are complete, review and close the change control.

## 11. PROCESS WHEN BLOOD SAMPLES HAVE ALREADY BEEN SENT TO THE LABORATORY

11.1 Laboratory to check location of donor hospital and refer to **INF1466** for H&I and **INF1583** for Virology to identify the appropriate back-up laboratory

11.2 Laboratory to notify back-up laboratory that the sample will be sent to them for processing and to confirm full address. Refer to **INF1712** for Virology Laboratory details, and **INF1713** for the H&I Laboratory details.

11.3 Laboratory to notify SN via Regional Contact Number of disruption and location of back-up laboratory to where samples have been sent.

11.4 SN to contact Transport Provider to arrange for samples to be collected from the laboratory to the back-up laboratory.

11.5 Laboratory to email OTDT Hub Operations as per 1. above

11.6 Hub Operations to notify all stakeholders as per 2. above

**⚠ Advice**

On receipt of the email to say service has been resumed, SNs will revert to normal practice of sending bloods to the usual laboratory.

**⚠ Advice**

Should the email service be unavailable, Hub Operations will inform SNs and RHoNs by sending out a brief message through the Regional Point of Contact number. Quality Assurance and Commissioning will be informed verbally or via a phone call. As soon as email is available, the

complete email will be sent to SNs, RHoNs, Quality Assurance and Commissioning in the usual method

## End of Procedure

## Definitions

- **RHoN** – Regional Head of Nursing
- **SN** – Specialist Nurse
- **QA** – Quality Assurance

## Related Documents/References

- Regional Handbooks – Stored in the Secure Contents Handbook
- **FRM4889** – Quality Risk Assessment record
- **INF1466** – Back-up Laboratories for Deceased Donor Tissue Typing Testing
- **INF1583** – Back-up Laboratories for Deceased Donor Virology Testing
- **INF1712** – Out of Hours Contact Details for Back-Up Virology Laboratories
- **INF1713** – Out of Hours Contact Details for Back-Up HLA Laboratories

## Appendices

N/A

## Training Plan for Documents:

| | | |
|---|---|---|
| **Type of Change** | Change to Existing Process | |
| **Stakeholders who require training** | **Trainee new to the process** | **Trainee trained to the previous revision.** |
| | Trainee specialist nurses | Specialist Nurses, Regional head of Nursing, Hub Operations, |
| **Knowledge required prior to training** | NA | Trained to previous version. |
| **Critical aspects of process** | This covers the process to follow if a laboratory is unable to process donor bloods. | |

**Training Plan:**

| | **Trainee new to the process** | **Trainee trained to the previous revision.** |
|---|---|---|
| **Recommended Training Method** | If not trained to version 4 then training to full document will be required | Trained onto version 7, read SOP. |
| **Assessment** | • FRM511 | • FRM511 |
| **Cascade Plan** | • Author authorises self-directed training> | • Author authorises self-directed training> |

**Training Score – Training Plan Risk Matrix (Collapsible – Click ▶ icon to open/close)**

Use the *Training Plan Risk Matrix* to identify the training method and assessment required.

The *Process Criticality Score* is determined by the potential impact on donor/patient safety and/or product quality using the table below for guidance:

| | Impact on Donor, Patient safety or product quality |
|---|---|
| 1. Negligible | A process whose failure, in full or in part, **cannot** impact product quality, patient/donor safety or the ability to supply products/services. |
| 2. Minor | A process whose failure, in full or in part, **may**:<br>(i) impact other processes thereby indirectly impacting product quality, patient/donor safety (e.g. harm only results where multiple failures in multiple processes align)<br>(ii) result in the discard of a small number of replaceable products and/or<br>(iii) result in an inconvenient delay to the supply of products/services (e.g. delay of 1-3hrs of non-urgent product/service). |
| 3. Moderate | A process whose failure, in full or in part, **may**: |

| | |
|---|---|
| | (i) indirectly impact product quality, patient/donor safety (e.g. harm only results where failures in more than 1 process align)<br>(ii) result in the discard of a medium number of replaceable products and/or<br>(iii) result in a temporary delay to the supply of products/services (e.g. delay of 4-12hours of non-urgent products/services). |
| 4. High | A process whose failure, in full or in part, is **likely** to:<br>(i) directly impact product quality, patient/donor safety<br>(ii) result in the discard of a large number of replaceable products<br>(iii) result in the discard of an irreplaceable product and/or<br>(iv) result in a delay to patient treatment. |
| 5. Very High | A process whose failure, in full or in part, is **certain** to:<br>(i) directly impact product quality, patient/donor safety<br>(ii) result in the discard of a large number of replaceable products<br>(iii) result in the discard of an irreplaceable product and/or<br>(iv) result in a delay to patient treatment. |
| **Process Criticality Score** | 3 |

The *Criticality of Change Score* is determined by assessing the nature of change(s) and complexity of the process using the table below for guidance.

| | Change to Trainee(s) |
|---|---|
| 1. Negligible | An existing process to which no material changes are made.<br><br>E.g. format changes, minor clarifications of existing practice, fixing typos. |
| 2. Minor | An existing process to which new information is added but where changes to existing knowledge and practices are minimal.<br><br>E.g. clarifications that tighten existing practices |
| 3. Moderate | An existing process of low complexity with material changes requiring different people to take action and/or people to change the tasks they perform.<br><br>E.g. new roles/responsibilities, changes to the order of existing tasks, new tasks |
| 4. High | A new process of moderate complexity, OR<br><br>An existing process of moderate complexity with material changes requiring different people to take action and/or changes to the way tasks are performed.<br><br>E.g. New roles and responsibilities, changes to tasks and/or the order in which tasks are performed, changes in equipment/materials, changes to values, measures or settings. |
| 5. Very High | A new process of high complexity, OR<br><br>An existing process of high complexity with material changes requiring different people to take action and/or changes to the way tasks are performed. |

| | |
|---|---|
| | E.g. New roles and responsibilities, changes to tasks and/or the order in which tasks are performed, changes in equipment/materials, changes to values, measures or settings. |
| **Criticality of Change Score** | 1 |

**Training Plan Risk Matrix:**

Process Criticality →

Criticality of Change ↓

| | 1. Negligible | 2. Minor | 3. Moderate | 4. High | 5. Very High |
|---|---|---|---|---|---|
| 1. Low | 1 | 2 | 3 | 4 | 5 |
| 2. Moderately Low | 2 | 4 | 6 | 8 | 10 |
| 3. Moderate | 3 | 6 | 9 | 12 | 15 |
| 4. High | 4 | 8 | 12 | 16 | 20 |
| 5. Very High | 5 | 10 | 15 | 20 | 25 |

| | **Trainee new to the process** | **Trainee trained to the previous revision.** |
|---|---|---|
| **Process Criticality Score** | 3 | |
| **Criticality of Change Score** | 1 | 1 |
| **Training Score** | 3 | 3 |

**Recommended Training Method and Assessment:**

| Training Score | Level of Risk | Examples of Training Methods | Examples of Assessment |
|---|---|---|---|
| 1 - 3 | Low | Read only | Record on FRM511 only |
| 4 - 8 | Manageable | Email, team brief, word brief | Knowledge/Observation Check & FRM511 |
| 9 - 14 | Medium/Significant | Formal training package | Knowledge/Observation Check & FRM511 or FRM5076 |
| 15 - 25 | High | Practical | FRM5076 or equivalent |