**Appendix 1:**

**FMT Serious Adverse Event/Reaction Root Cause Analysis (RCA)**

**Introduction**

This form is to be used to conduct a RCA following a serious adverse event or reaction relating to an infection that occurred within 48 hours of the patient receiving a Faecal Microbiota Transplant (FMT), prepared and administered by the protocols defined in UoB-ATF-QCD-0199 Preparation of Faecal Microbiota Transplants and the UoBMTC FMT Clinical Protocol guideline. Such an infection will be considered to have been likely or possibly due to members(s) of the flora in the FMT at the time of delivery. A gram-negative bacteraemia (e.g. “coliform”), or unexplained enteric infection, e.g. norovirus are examples.

This RCA must be conducted within 5 days of the incident, and no further FMT treatment will be dispatched from the same donor samples until the review process has been done, corrective and preventative actions completed, and the full process is confirmed as safe.

The overall aim of the RCA process is to:

* Review all the necessary documentation to determine if there is a clear cause or route of transmission, from the FMT, or from any another source.
* To identify and address any shortcomings in the process.
* Develop and implement corrective and preventative actions.
* Address any wider issues with this incident, e.g. bay/ward norovirus outbreak. The documentation arising from that should be included as an addendum in this report.
* To give reassurance to all users and relevant organisations (BMTC, local Trust, MHRA).

The RCA review group must include:

* Professor P Hawkey UoBMTC Director
* Dr V McCune UoBMTC Scientific Advisor
* Professor T Iqbal, Dr Mohammed Nabil Quraishi or Dr Naveen Sharma, UoBMTC Clinical leads
* Patient’s Consultant
* Ward nursing lead (or alternate)
* Trust Infection Control nurse, as necessary
* Qualified Person
* Dr Sue Manzoor UoBMTC Production Manager
* Carol Evans UoBMTC Quality Manager
* Sahida Shabir MTC Service Manager

The RCA can be conducted by teleconference. The following proforma should be completed in full.

It is a requirement of Specials use of an unlicensed medicine that:

* manufacturers should report any suspected adverse drug reaction immediately and in no case later than 15 calendar days from receipt, stating that the product is unlicensed. It is a mandatory requirement to electronically report suspected ADRs. The ICH-E2B international standard electronic report should be used and the report should be electronically submitted via the EudraVigilance European Gateway (see MHRA or EMA websites for more details).
* prescribers or pharmacists supplying the “special” should report using a Yellow Card form or an electronic Yellow Card (found at http://www.mhra.gov.uk/yellowcard), stating the manufacturer and indicating that the product is unlicensed.

|  |  |
| --- | --- |
| **Patient details** |  |
| **NHS Trust** |  |
| **Patient Name** |  |
| **Hospital number** |  |
| **Date of Birth** |  |
| **Indication for FMT** |  |
| **Please provide evidence for indication to treat** |  |
| **Place of FMT administration** |  |
| **Date of admission** |  |
| **Date and time of administration** |  |
| **History of the patient** |  |
| **Past medical history and co-morbidities** |  |
| **Relevant microbiology results in the 30 days prior to FMT, include date of collection and laboratory numbers** |  |