**DIRECTORATE OF RESEARCH AND INNOVATION**

**Note to File**

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| **Protocol Title:** | |  | | |
| **R&D Number:** | |  | | |
| **Principal Investigator:** | |  | | |
| **Note to File Title:** | | Location of Adverse Event (AE) logs | | |
| The Trust uses an electronic patient record (EPR) system to record clinical notes, this includes records of Adverse Events (AEs).  The source data for these clinical notes are the dynamic electronic system (including the associated metadata). Based on the MHRA ‘GXP’ Data Integrity Guidance; as the system permits dynamic storage of the data, it is not appropriate for static (printed) data to be retained in preference to dynamic (electronic) data as these would be ‘flat files’ that do not represent the complete record. Therefore, the Investigator Site File (ISF) will not contain printed clinical data, such as AE logs, as these records will be stored on the electronic system.  The EPR will be available for review during monitoring visits and the Sponsor will be informed of relevant clinical information (such as Serious Adverse Events/Reactions (SAE/Rs) in accordance with the protocol, Trust procedures and/or Sponsor requirements.  Templates have been built to include all information required as per the Sponsor’s paper AE logs in the EPR. By signing this note to file, the CRA on behalf of the Sponsor/Sponsor is agreeing that they have reviewed the electronic AE logs and that these are equivalent to the paper logs. | | | | |
| **File Note Author** | | | | |
| **Name:** |  | | **Role:** |  |
| **Signature:** |  | | **Date:** |  |
| **Clinical Research Associate on behalf of the Sponsor/Sponsor** | | | | |
| **Name:** |  | | **Role:** |  |
| **Signature:** |  | | **Date:** |  |
| **Principal Investigator** | | | | |
| **Name:** |  | |  |  |
| **Signature:** |  | | **Date:** |  |