Template Case Note Labels 1 – ‘safety reporting required’

This Template should be used in conjunction with R&D/S24

**IT IS THE RESPONSIBILITY OF ALL USERS OF THIS TEMPLATE TO ENSURE THAT THE CORRECT VERSION IS BEING USED**

All staff should regularly check the R&D Unit’s website and/or Q-Pulse for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive versions of all R&D Unit SOPs appear online. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the R&D Unit website: https://www.research.yorkhospitals.nhs.uk/sops-and-guidance-/ and/or Q-Pulse

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| Template Reference: | R&D/T26 |
| Version Number: | 5.0 |
| Author: | Mags Szewczyk |
| Implementation date of current version: | 18th January 2022 |

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| Approved by: | Name/Position: | Lydia Harris, Head of R&D |
| Signature: |  |
| Date: | 21st December 2021 |
|  | Name/Position: | Sarah Sheath, SOP Controller |
|  | Signature: |  |
|  | Date: | 21st December 2021 |

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| This Template will normally be reviewed every 3 years unless changes to the legislation require otherwise |

**Version History Log**

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

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| **Version** | **Date Implemented** | **Details of significant changes** |
| 1.0 | 17th December 2012 |  |
| 2.0 | 4th January 2016 |  |
| 3.0 | 21st August 2017 | Removal of reference to R&D newsletter |
| 4.0 | 2nd October 2019 | Change of link to R&D website.  References to CPD (Electronic Health Records) added to reflect the use of CPD *Research Referrals & Contacts* for clinical research purposes - this is a part of the [NHS initiative to replace patients’ paper medical records with electronic health records](https://digital.nhs.uk/about-nhs-digital/corporate-information-and-documents/our-strategy).  Please note: during the transition time (until the paper medical records get fully transferred onto CPD) the complete medical record for a patient consists of both: paper notes & CPD records. |
| 5.0 | 18th January 2022 | Change of label size. Change of Trust name |

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| **R&D ALERT**  **R&D ALERT**  **R&D ALERT**  **R&D ALERT**  **RESEARCH PARTICIPANT**  Abbreviated Study Name:  CHECK MEDICAL RECORDS FOR DETAILS (CPD & PAPER)  IF PATIENT ADMITTED ADVISE RESEARCH TEAM:  If study/drug info required out of normal working hours contact the on-call Pharmacist via the switchboard  KEEP IN ORIGINAL FORM DO NOT DESTROY RECORDS BEFORE: | **RESEARCH PARTICIPANT**  Abbreviated Study Name:  CHECK MEDICAL RECORDS FOR DETAILS (CPD & PAPER)  IF PATIENT ADMITTED ADVISE RESEARCH TEAM:  If study/drug info required out of normal working hours contact the on-call Pharmacist via the switchboard  KEEP IN ORIGINAL FORM DO NOT DESTROY RECORDS BEFORE:  **RESEARCH PARTICIPANT**  Abbreviated Study Name:  CHECK MEDICAL RECORDS FOR DETAILS (CPD & PAPER)  IF PATIENT ADMITTED ADVISE RESEARCH TEAM:  If study/drug info required out of normal working hours contact the on-call Pharmacist via the switchboard  KEEP IN ORIGINAL FORM DO NOT DESTROY RECORDS BEFORE:  **RESEARCH PARTICIPANT**  Abbreviated Study Name:  CHECK MEDICAL RECORDS FOR DETAILS (CPD & PAPER)  IF PATIENT ADMITTED ADVISE RESEARCH TEAM:  If study/drug info required out of normal working hours contact the on-call Pharmacist via the switchboard  KEEP IN ORIGINAL FORM DO NOT DESTROY RECORDS BEFORE:  **RESEARCH PARTICIPANT**  Abbreviated Study Name:  CHECK MEDICAL RECORDS FOR DETAILS (CPD & PAPER)  IF PATIENT ADMITTED ADVISE RESEARCH TEAM:  If study/drug info required out of normal working hours contact the on-call Pharmacist via the switchboard  KEEP IN ORIGINAL FORM DO NOT DESTROY RECORDS BEFORE:  **RESEARCH PARTICIPANT**  Abbreviated Study Name:  CHECK MEDICAL RECORDS FOR DETAILS (CPD & PAPER)  IF PATIENT ADMITTED ADVISE RESEARCH TEAM:  If study/drug info required out of normal working hours contact the on-call Pharmacist via the switchboard  KEEP IN ORIGINAL FORM DO NOT DESTROY RECORDS BEFORE:  **RESEARCH PARTICIPANT**  Abbreviated Study Name:  CHECK MEDICAL RECORDS FOR DETAILS (CPD & PAPER)  IF PATIENT ADMITTED ADVISE RESEARCH TEAM:  If study/drug info required out of normal working hours contact the on-call Pharmacist via the switchboard  KEEP IN ORIGINAL FORM DO NOT DESTROY RECORDS BEFORE: | **&D ALERT**  **R&D ALERT**  **R&D ALERT**  **R&D ALERT** |
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