A picture containing diagram

Description automatically generated

**Assessment and monitoring of remote IMP storage**

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| **Study Title:** | Tranexamic acid for hyperacute spontaneous IntraCerebral Haemorrhage (TICH-3) |
| **EudraCT No:** | 2021-001050-62 |
| **Chief Investigator:** | Professor Nikola Sprigg |
| **Site:** |  |
| **Principal Investigator:** |  |

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| --- | --- | --- | --- |
| **Description of proposed area for IMP** | | **Suitable for use (Yes/No)** | **Comments** |
| Security measures in place (location, access controls etc) |  |  |  |
| Size and description of proposed storage area (shelves, cupboards etc) |  |  |  |
| If not for exclusive use, what controls are in place to segregate IMP from other medicines |  |  |  |
| Description of IMP management. The following should be available. | | | |
| Dispensing procedure with documented training for research team | Select the next lowest numbered available treatment pack. Prescribing and administration guide to be followed. |  |  |
| Accountability procedure with documented training for research team | Prescribing and administration guide to be followed. |  |  |
| A procedure for transfer of IMP between pharmacy and proposed storage facility |  |  |  |
| Proposed methods of maintaining pharmacy oversight |  |  |  |
| Copies of accountability logs supplied to pharmacy (agree time interval and/or trigger factors) |  |  |  |
| Pharmacy to monitor facilities and IMP management (agree time interval and/or trigger factors) |  |  |  |
| Other measures |  |  |  |

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| Pharmacy Approval (Clinical Trials Pharmacist) or delegated responsible person | | | |
| Signature: |  | Print name: |  |
| Title: |  | Date: |  |

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| Confirmation of agreed arrangements by research team | | | |
| Signature: |  | Print name: |  |
| Title: |  | Date: |  |