**DIRECTORATE OF RESEARCH AND INNOVATION**

**Study Amendment Tracker**

|  |  |
| --- | --- |
| **R&D Number:** |  |
| **Short Title of Study:**  |  |
| **Principal Investigator (PI):** |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Number** | **Amendment description and rationale***(as per cover letter/amendment form)* | **Documents updated and new version numbers** *(often found in approval letters)* | **Substantial or Non-Substantial?** *(dates are in cover letters/approval letters)* | **Has relevant training been completed and documented?** | **Person completing tracker** |
| **Name**  | **Date** |
|  |  |  | [ ]  **Substantial**

|  |  |  |
| --- | --- | --- |
|  | Date informed | Date approved |
| R&D | DD-MMM-YYYY | DD-MMM-YYYY |
| MHRA | DD-MMM-YYYYor NA | DD-MMM-YYYYor NA |
| REC | DD-MMM-YYYYor NA | DD-MMM-YYYYor NA |
| HRA | DD-MMM-YYYY | DD-MMM-YYYY |

[ ]  **Non-Substantial**

|  |  |  |
| --- | --- | --- |
|  | Date informed | Date approved |
| HRA | DD-MMM-YYYY | DD-MMM-YYYY |
| R&D | DD-MMM-YYYY | DD-MMM-YYYY |

 | **Y/N** |  | DD-MMM-YYYY |
|  |  |  | [ ]  **Substantial**

|  |  |  |
| --- | --- | --- |
|  | Date informed | Date approved |
| R&D | DD-MMM-YYYY | DD-MMM-YYYY |
| MHRA | DD-MMM-YYYYor NA | DD-MMM-YYYYor NA |
| REC | DD-MMM-YYYYor NA | DD-MMM-YYYYor NA |
| HRA | DD-MMM-YYYY | DD-MMM-YYYY |

[ ]  **Non-Substantial**

|  |  |  |
| --- | --- | --- |
|  | Date informed | Date approved |
| HRA | DD-MMM-YYYY | DD-MMM-YYYY |
| R&D | DD-MMM-YYYY | DD-MMM-YYYY |

 | **Y/N** |  | DD-MMM-YYYY |