**Guidance**

You must obtain your Sponsor’s approval before either implementing any changes or notifying other review bodies ie, NHS REC and NHS R&D.

Send a copy of the amendment tool (downloaded from IRAS) and your updated or new documents to researchgovernance@abdn.ac.uk for Sponsor approval and categorisation of the amendment.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Amendment number** | **Document title** | **Previous version number and date** | **Revised version number and date** | **Classification and Date of approval by sponsor** | **Amendment Category A/B/C** | **Bodies to which amendment has been submitted** | **Approval/ Implementation Date**  |
| **Version** | **Date** | **Version** | **Date** | **Substantial** | **Non-Substantial** | **Non-Notifiable** |
| 001 | ProtocolParticipant information sheet | 11 | 10/10/1710/10/17 | 22 | 01/12/1710/12/17 | [x]  | [ ]  | [ ]  |  | REC | [x]  | 14/01/18 |
| R&D | [x]  | 20/01/18 |
| Date:24/12/17  | Date: N/A | Date:N/A | PBPP | [x]  | 20/03/18 |
| Other (specify) | [ ]  |  |
| 002 | ProtocolParticipant information sheetHealth Questionnaire  | 221 | 10/10/1710/10/1710/10/17 | 332 | 04/04/1804/04/1804/04/18 | [x]  | [ ]  | [ ]  |  | REC | [x]  | 04/05/18 |
| R&D | [x]  | 05/06/18 |
| Date:07/04/18 | Date: N/A | Date:N/A | PBPP | [x]  | 10/08/18 |
| Other (specify) | [ ]  |   |

Example:

|  |  |
| --- | --- |
| **Protocol Title** |  |
| **Chief Investigator** |  |  **IRAS Number** |  |
| **Amendment number** | **Document title** | **Previous version number and date** | **Revised version number and date** | **Classification and Date of approval by sponsor** | **Amendment Category A/B/C** | **Bodies to which amendment has been submitted** | **Approval/ Implementation Date**  |
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|  |  |  |  |  |  | [ ]  | [ ]  | [ ]  |  | REC | [ ]  |  |
| R&D | [ ]  |  |
| Date: | Date:  | Date: | PBPP | [ ]  |  |
| Other (specify) | [ ]  |  |
|  |  |  |  |  |  | [ ]  | [ ]  | [ ]  |  | REC | [ ]  |  |
| R&D | [ ]  |  |
| Date: | Date:  | Date: | PBPP | [ ]  |  |
| Other (specify) | [ ]  |  |

*Add a new row for each amendment.*