**FRM033 RECORD OF MEDICINES RECALL AND ACTION TAKEN FOR IMPS AND MEDICATIONS IN RPH SPONSORED studies**

Sponsor to Complete

|  |  |  |
| --- | --- | --- |
| Clinical trial affected by recall / CI |  | |
| R&D Reference Number |  | |
| Message Received By (name and job) |  | |
| Date and Time |  | |
| Recall level | 1 2 3 4 | |
| Reason for recall | (or attach memo) | |
| Drug name, form and strength |  | |
| Pack Size |  | |
| Manufacturer / Supplier |  | |
| Legal status of drug | Licensed Unlicensed Special For clinical trial use only | |
| Batch numbers affected (or attach list) |  | |
| MHRA (CTU and Defective Medicines Report centre) contacted | Yes / No  Outcome of discussion: | |
| Actions requested at Site |  | |
| Site Actions | | |
| Site name/number |  |  |
| Staff Actioning Recall |  |  |
| Product distributed to trial participants | Yes – attach list of subject numbers who received drug and dispensing dates | No |
| Relevant staff members informed (tick if informed) | CI or PI  Research Nurse  Pharmacy team  R&D trial manager / trial co-ordinator | |
| Action taken (by who)  For patient level recalls please document separately in patient notes any specific actions |  | |
| Recall Actions complete | (Signature & Date) | |
| Comments |  | |

**Once complete please return for to the Clinical Trial Manager / Sponsor representative.**

**File in Investigator Site File and Pharmacy File (copy)**

**Recall Levels:**

NatPSA (Formerly Class 1) (Immediate action including Out of Hours). Where the defect presents a risk of death or disability

Class 2 (recall - action within 48 hours) Defect may cause harm but is not life threatening

Class 3 (recall - action within 5 days) Defect is unlikely to cause harm

Class 4 (medicines notification, caution in use, no recall required) No threat to patients

Company led medicines recall – as per alert