Dose Escalation Authorisation checklist

This checklist is to be completed and signed by the Principal Investigator at UHBW before they enact a dose escalation approval for a study. The document must then be circulated appropriately and kept on file.

If a study protocol has more than a single dose escalation, a checklist most be completed, signed and circulated for each dose escalation.

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| --- | --- |
| **Study Information** | |
| **Study title:** |  |
| **R&D reference number** |  |
| **IRAS number** |  |
| **Current approved protocol**  **date and version number** |  |
| **Principal Investigator at UHBW** |  |
| **Dose Escalation information** | |
| **Is there more than one dose escalation planned in the protocol?** | **Yes / No** *(delete as required)* |
| **If yes, please describe or otherwise indicate to which dose escalation decision this form relates** |  |
| **Date the dose escalation data (e.g. interim data report or equivalent) received at site** |  |
| **Date of study dose escalation meeting** |  |
| **Names/ roles of those present at dose escalation meeting** |  |
| **Study dose escalation decision/ outcome of meeting** |  |

If in doubt, please refer to:

**SOP\_029 Management of dose escalation in research studies at UHBW**

**Study Dose escalation assessment and mitigation plan** that was completed as part of the C&C checks at site set up (**TMPL\_128**)

|  |  |
| --- | --- |
| **Dose Escalation Authorisation – Principal investigator declaration** | |
| **As Principal Investigator (PI) for the above-named study I have medical responsibility for the trial subjects under my care**  I have received and reviewed the dose escalation data (e.g. interim data report or equivalent) and this document is filed in the investigator site file 🞎  I have received and reviewed the notes from the dose escalation meeting and these records are filed in the investigator site file 🞎  I am satisfied that I have sufficient information about the data reviewed for the DE meeting (dated \_\_/\_\_\_/\_\_\_\_) used for this dose escalation decision in order that I can make this decision for the participants under my care 🞎  I give authorisation for the DE to proceed 🞎 | |
| **Principal Investigator signature** |  |
| **Date** |  |

Once dose escalation is approved by PI, this form should be circulated to:

***Study delivery team*** *and filed in Investigator Site File*

***UHBW Clinical Trials Pharmacy*** *and filed in Pharmacy File*

***UHBW R&D*** *and filed with study documentation*

***Sponsor Representative***