|  |  |
| --- | --- |
| **Study Details** | |
| Study Title |  |
| Chief Investigator |  |
| Protocol  *(version / date)* |  |
| Current Dose |  |
| Proposed next dose *(as defined by protocol / DMC Charter)* |  |
| Data Monitoring Committee (DMC) Data Review Report  *(version / date)* |  |
| DMC Open Minutes (*date)* |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Part 1: Co-Sponsor authorisation to proceed with dose escalation**  *(to be completed by Sponsor Representative, or designee)* | | | | |
| (✓) | **Yes** | **No** | | |
| DMC Data Review Report Received |  |  | | |
| DMC Open Minutes Received |  |  | | |
| Dose progression should continue in line with DMC recommendations |  |  | | |
| Comments |  | | | |
| Print Name (Title) |  | | | |
| Signature |  | | Date |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Part 2: CI authorisation to proceed with dose escalation**  *(to be completed by CI)* | | | | |
| (✓) | **Yes** | **No** | | |
| DMC Data Review Report Received |  |  | | |
| DMC Open Minutes Received |  |  | | |
| Dose progression should continue in line with DMC recommendations |  |  | | |
| Comments *(include description of clinical basis for agreement or disagreement to escalate)* |  | | | |
| Print Name |  | | | |
| Signature |  | | Date |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Part 3: PI authorisation to proceed with dose escalation**  *(to be completed by PI)* | | | | |
| Site Name |  | | | |
| (✓) | **Yes** | **No** | | |
| DMC Data Review Report Received |  |  | | |
| DMC Open Minutes Received |  |  | | |
| Dose progression should continue in line with DMC recommendations |  |  | | |
| Comments *(include description of clinical basis for agreement or disagreement to escalate)* |  | | | |
| Print Name |  | | | |
| Signature |  | | Date |  |

**DOSE PROGRESSION CANNOT PROCEED AT SITE UNTIL AUTHORISED BY THE DMC, SPONSOR, CI AND PI.**

**ALL SIGNATURES MUST BE COMPLETED AND DECISION CIRCULATED AT SITE PRIOR TO DOSING**

*Please send completed form to* [resgov@accord.scot](mailto:resgov@accord.scot)

*Completed form to be filed in section 7 of the Investigator Site File (ISF), copy in section 7 of the Trial Master File (TMF) and / Sponsor File. Associated DMC minutes and dose progression DMC Report should be appended.*