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| --- | --- | --- | --- |
| **Study Sponsor:** |  | **Principal Investigator:** |  |
| **Protocol number:**  |  | **Site number:** |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name of Principal Investigator**  | **Principal Investigator’s Signature**\* | **Principal Investigators Initials** | **Start Date****(dd/mmm/yy)** | **End Date****(dd/mmm/yy)** |
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**\*My signature confirms/acknowledges that the information contained here is accurate and that;**

* **I will remain responsible for the overall study conduct and reported data.**
* **I will ensure study oversight.**
* **I will authorise the delegation of study-related tasks to each individual as listed.**
* **The study tasks listed will only be delegated by me to skilled and qualified staff appropriately trained for the role.**
* **I will ensure that all personnel assisting in the conduct of the study are informed about their obligations and will not have performed any delegated**

**study related tasks prior to appropriate delegation and completion of study training appropriate to the role.**

* **I will ensure that site staff receives, in a timely manner, the appropriate information and training.**
* **I will ensure that any changes in staff or delegated study-related task will be recorded in a timely manner.**

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| --- | --- | --- | --- |
|  | Delegated PI responsibilities when PI is NOT on extended leave (less than 6 weeks)\* |  | Obtain informed consent\* ® |
|  | Determine subject eligibility based on inclusion / exclusion criteria\* ® |  | Assess and document physical examination including lymphoma symptoms\* ® |
|  | Evaluate/assess AE/SAE (for causality and relatedness) \* ® |  | Evaluate/assess study specific reports (ECG, imaging scans, pathology reports)\* ® |
|  | IP Dose Management \* ® |  | Review and sign eCRF \*  |
|  | Unblinding (if applicable) \*  |  | ECOG Assessment, Vital signs, weight, height, B-symptoms |
|  | Obtain and document medical history |  | Review, grade, and record, as per protocol serious adverse events and adverse events  |
|  | Review and escalation of abnormal results and assessments (lab reports / ECGs / vital signs, imaging)  |  | Reporting of serious adverse events  |
|  | Review, grade, and record medical history  |  | Review and record concomitant medications |
|  | Instruction on IP administration |  | IP administration  |
|  | Access IWRS / IVRS  |  | Drug Compliance |
|  | CRF completion / EDC entry and Data query resolution |  | Collects samples |
|  | Processes and ships biological samples IATA trained |  |  Delegates and Trains pharmacy staff |
|  | Investigator Site File Maintenance / Essential Documents |  | Coordinates HREC / RGO Communications  |
|  | Access safety portal for management of safety updates |  | Other |
|  | Other |  | Other |
|  | Other |  | Other  |
|  | Other  |  | Other  |
| \*Tasks delegated to Sub-I who is delegated task 1®Tasks delegated to Sub-Is ONLY |

**LIST OF AUTHORISED RESPONSIBILITIES (PI IS RESPONSIBLETO ENSURE STUDY STAFF ARE TRAINED, EDUCATED AND QUALIFIED TO PERFORM EACH DELEGATED TASK**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Print name** | **Signature** | **Initials** | **Study role** | **Delegated tasks (tick all applicable)** | **Start date of delegation****(dd/mmm/****yyyy)** | **End date of delegation****(dd/mmm/****yyyy)** |
|  |  |  |  | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** | **11** | **12** | **13** | **14** | **15** | **16** | **17** | **18** | **PI initials:** | **PI initials:** |
| **19** | **20** | **21** | **22** | **23** | **24** | **25** | **26** | **27** | **28** | **29** | **30** | **31** | **32** | **33** | **34** | **35** | **36** | **Date:** | **Date:** |
|  |  |  |  | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** | **11** | **12** | **13** | **14** | **15** | **16** | **17** | **18** | **PI initials:** | **PI initials:** |
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| **Print name** | **Signature** | **Initials** | **Study role** | **Delegated tasks (tick all applicable)** | **Start date of delegation****(dd/mmm/****yyyy)** | **End date of delegation****(dd/mmm/****yyyy)** |
|  |  |  |  | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** | **11** | **12** | **13** | **14** | **15** | **16** | **17** | **18** | **PI initials:** | **PI initials:** |
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| **Print name** | **Signature** | **Initials** | **Study role** | **Delegated tasks (tick all applicable)** | **Start date of delegation****(dd/mmm/****yyyy)** | **End date of delegation****(dd/mmm/****yyyy)** |
|  |  |  |  | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** | **11** | **12** | **13** | **14** | **15** | **16** | **17** | **18** | **PI initials:** | **PI initials:** |
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| **19** | **20** | **21** | **22** | **23** | **24** | **25** | **26** | **27** | **28** | **29** | **30** | **31** | **32** | **33** | **34** | **35** | **36** | **Date:** | **Date:** |

I confirm that the information contained in this document is accurate and complete. PI dated signature here confirms the end date of all staff remaining on the log at study closure (To be completed by the Principal Investigator at the end of the study).

|  |  |  |
| --- | --- | --- |
| **Principal Investigator name:** | **Signature:** | **Date**: |
|  |  |  |