# **STAFF SIGNATURE AND DELEGATION LOG**

|  |  |  |
| --- | --- | --- |
| **IRAS ID** | **Protocol Title** | **Name of Participating Organisation** |
| **237309** | **The UK-Irish Atopic eczema Systemic Therapy Register (A-STAR)** |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name of Principal Investigator** | **Principal Investigator Signature1** | **PI’s Initials** | **Start**  **(DD-MMM-YYYY)** | **End**  **(DD-MMM-YYYY)** |
|  |  |  |  |  |

**1**My signature confirms/acknowledges that the information contained in this delegation log is accurate and that:

1. I will conduct the study in accordance with the protocol and remain responsible for the overall study conduct at the participating organisation and for the reported data.
2. I will ensure study oversight.
3. I will authorise the delegation of study-related tasks to each individual as listed.
4. The study tasks listed will only be delegated by me to skilled and qualified staff appropriately trained for the role.
5. 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.
6. I will ensure that participating organisation staff receive, in a timely manner, the appropriate information and training.
7. I am not involved in any regulatory or misconduct litigation or investigation by any regulatory authority and no data produced by me in any previous clinical Study has been rejected because of concerns as to its accuracy or because it was generated by fraud.
8. Neither I, nor any dependents, have entered into and will not enter into arrangements, financial or otherwise, with any third party providing support, products and/or services to the study that would present a conflict of interests.
9. I will ensure that any and all changes in staff or delegated study-related task will be recorded in a timely manner.
10. I consent to the sponsor, and to any relevant third party providing support, products and/or services to the Study, holding my name and other relevant details on an appropriate database for the purpose of communicating with me in relation to the study.

**Study Task Key:**

The sponsor may detail in the below key the main study activities that the Principal Investigator can delegate to staff at the participating organisation. The task list and delegation log are intended to be maintained as an up to date document throughout the duration of the study at the participating organisation.

|  |  |
| --- | --- |
| 1. Overall responsibility for study at Site (including delegation and authorisation of study related duties and responsible for local financial management where appropriate). | 10. Study sample collection. |
| 2. Medical care and supervision of study patients. | 11. Processing and shipping of study samples. |
| 3. Obtaining informed consent and signing consent forms. | 12. Regulatory body interactions. |
| 4. Screening of participants and inclusion / exclusion criteria review. | 13. Authorisation of CRFs. |
| 5. Physical exam / clinical evaluations. | 14. Archiving of study data. |
| 6. CRF completion / data entry. | **Please specify below any other duties specific to above study:** |
| 7. Resolving data queries. | 15. Bioresource- related sample collection (microbiome swabs, tape stripping, skin biopsy for the subjects above 16 years old) – applicable for Bioresource sites only |
| 8. Maintaining Investigator Site File. |  |
| 9. Reviewing & reporting Adverse Events & Serious Adverse Events. |  |

|  |  |  |
| --- | --- | --- |
| **IRAS ID** | **Protocol name** | **Name of participating organisation** |
| **237309** | **The UK-Irish Atopic eczema Systemic Therapy Register (A-STAR)** |  |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Name** | **Study Role** | **Delegated Duties** | **Staff Initials** | **Staff Signature2** | **Principal Investigator Signature** | **Start Date**  **(DD-MMM-YYYY)** | **End Date**  **(DD-MMM-YYYY)** |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

|  |  |  |
| --- | --- | --- |
| **IRAS ID** | **Protocol name** | **Name of participating organisation** |
| **237309** | **The UK-Irish Atopic eczema Systemic Therapy Register (A-STAR)** |  |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Name** | **Study Role** | **Delegated Duties** | **Staff Initials** | **Staff Signature2** | **Principal Investigator Signature** | **Start Date**  **(DD-MMM-YYYY)** | **End Date**  **(DD-MMM-YYYY)** |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

**2**My signature confirms/acknowledges that I accept the assigned study task/s and that:

* I am not involved in any regulatory or misconduct litigation or investigation by any regulatory authority, and no data produced by me in any previous clinical Study has been rejected because of concerns as to its accuracy or because it was generated by fraud.
* I consent to the sponsor, and to any relevant third party providing support, products and/or services to the study, holding my name and other relevant details on an appropriate database for the purpose of communicating with me in relation to the study.

|  |  |  |
| --- | --- | --- |
| **To be completed by the Principal Investigator at the end of the study** | | |
| I confirm that the information contained in this Delegation Log is accurate and complete. | | |
| **Principal Investigator Name** | **Principal Investigator Signature** | **Date**  **(DD-MMM-YYYY)** |
|  |  |  |