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SITE TRAINING LOG

ICON Study Number:	2433/0006	Sponsor Protocol Number:	SP304203-06
PI Name:		Site Number:	

Date of Training	Training**	Trainer Full Name	Trainer Signature	Trainee Full Name	Trainee Role*	Trainee Signature	PI Initials and Date

* Role: includes but is not limited to sub-Investigators, study coordinators, pharmacists, lab technicians, etc.

** Training:

1 Protocol & Amendments
2 IDB
3 Subject Consenting Process
4 Blinding Procedures
5 IP Receipt/Storage/Re-Supply/Accountability/Return
6 IP Preparation
7 IP Administration/Transfer
8 IVR
9 Laboratory Procedures
10 EDC System/CRF Completion
11 Investigator Site File
12 Adequate Source Documentation
13 AE / SAE Reporting Process
14 ICH/GCP Responsibilities
15 Query Processing
16 Other, specify _____
17 Other, specify _____
18 Other, specify _____
19 Other, specify _____
20 Other, specify _____

PI Signature _____ Date_____ (To be signed by PI when page is complete, or at study closure)

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SITE RESPONSIBILITY LOG

Sponsor Name:	**Synergy Pharmaceuticals, Inc.**	**Sponsor Protocol Number:**	**SP304203-06**
Site Number:		**ICON Number:**	**2433/0006**
PI Name:		**Page:**	**[ ] of [ ]**

Print Full Name	Signature (Signature confirms responsibilities in the study and accepts the terms of the Data Privacy Consent.)	Initials	Role*	Delegated Tasks (Use the codes from the key)	Duration on study			
					Start Date	PI Initials and Date**	End Date	PI Initials and Date

This form must be completed by all personnel involved in the study.

(*)Role: Includes but is not limited to Sub-Investigators, study coordinators, pharmacists and lab technicians, etc.

(**) By initialing the PI confirms that the relevant staff member was trained for the required delegated activities and will operate under the PI's oversight. Project specific training in tasks must be completed prior to performing any associated study procedure which differs from normal clinical practice and documented on project specific training log.

Key to Delegated Tasks:

1. Obtain Informed Consent***
2. Medical History***
3. Perform Physical Exam***
4. Confirm Eligibility of Subjects (Screening and/or Randomization)***
5. Safety Review and Oversight***
6. AE Causality***
7. Prescribe and/or Titrate IP***
8. Prepare IP
9. Dispense IP
10. QC/Verification of Dispensed IP (Only if required by Sponsor)
11. Administer IP
12. Break the IP blind(if applicable)***
13. Draw Lab Samples
14. Process Lab Samples
15. CRF Completion and Corrections
16. Sign DM Queries
17. Other, Specify: _____
18. Other, Specify: _____
19: Other, Specify: _____

***Task for MD only (or delegate as permitted by local regulations and confirmed by documented certification or evidence on CV)**