

## UCDHS COORDINATOR TRAINING CHECKLIST

| ACTIVITY                     | Trained by:<br>(Trainer date & initials) | Confirmation of understanding<br>(coordinator date & initials) |
|------------------------------|--|--|
| <b>Research Overview</b>     |  |  |
| Protection of human subjects |  |  |
| Role of research staff       |  |  |
| Role of monitors             |  |  |
| Regulations                  |  |  |
| GCP                          |  |  |
| SOPs                         |  |  |
|                              |  |  |
| <b>Review of Protocol</b>    |  |  |
| Summary                      |  |  |
| Inclusion/Exclusion          |  |  |
| Randomization                |  |  |
| Visits/Procedures            |  |  |
| Clinical events/endpoints    |  |  |
| Adverse events               |  |  |
| Amendments                   |  |  |
|                              |  |  |
| <b>Informed Consent</b>      |  |  |
| Purpose                      |  |  |
| Required elements            |  |  |
| Procedures                   |  |  |
| Read                         |  |  |
| Initials                     |  |  |
| Signatures & dates           |  |  |
| Documentation in chart       |  |  |
| QA check                     |  |  |
| HIPAA/PHI                    |  |  |
|                              |  |  |
| <b>Vitals</b>                |  |  |
| Weight                       |  |  |
| Height                       |  |  |
| Blood pressure               |  |  |
| Heart rate/pulse             |  |  |
| Respiration                  |  |  |
| Temperature                  |  |  |
| Conversions                  |  |  |
| <b>Abnormal Test Results</b> |  |  |
| Labs                         |  |  |
| Other tests                  |  |  |
|                              |  |  |

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|--|--|--|
| <b>Lab Preparation &amp; Shipping</b>    |  |  |
| Tubes                                    |  |  |
| Blood draw                               |  |  |
| Centrifuges                              |  |  |
| Safety precautions                       |  |  |
| Specimen handling                        |  |  |
| Waste handling                           |  |  |
|  |  |  |
| <b>Adverse Events</b>                    |  |  |
| Definition                               |  |  |
| AE log                                   |  |  |
|  |  |  |
| <b>SAEs/Endpoints</b>                    |  |  |
| Definition and the difference            |  |  |
| Reporting of SAEs/Endpoints              |  |  |
| Sponsor                                  |  |  |
| IRB                                      |  |  |
|  |  |  |
| <b>Concomitant meds &amp; treatments</b> |  |  |
| Definition                               |  |  |
| Start date & stop date                   |  |  |
| Dosing                                   |  |  |
| Logs                                     |  |  |
|  |  |  |
| <b>Study Management</b>                  |  |  |
| Source documentation                     |  |  |
| CRF completion                           |  |  |
| Screen/Consent log                       |  |  |
| Enrollment log                           |  |  |
| Communication with physicians            |  |  |
| Communication with other staff           |  |  |
| Visit schedules & windows                |  |  |
| Queries                                  |  |  |
|  |  |  |
| <b>Drug Accountability</b>               |  |  |
| Inventory                                |  |  |
| Dispensing logs                          |  |  |
| Documentation, labels, etc.              |  |  |
| Restricted access                        |  |  |
| Patient compliance                       |  |  |
| Unblinding                               |  |  |
| Drug destruction policies                |  |  |
| IVRS                                     |  |  |
|  |  |  |
|  |  |  |

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| <b>Regulatory Compliance</b>               |  |  |
| Critical documents                         |  |  |
| Who needs to see it?                       |  |  |
| Correspondence                             |  |  |
| IND safety reports                         |  |  |
| IRB notification                           |  |  |
| <b>Study Patient Evaluation</b>            |  |  |
| Screen potential patient                   |  |  |
| Screen documentation                       |  |  |
| Screening CRF                              |  |  |
| Enroll eligible participant                |  |  |
| Randomize new patient                      |  |  |
| Dispense/dose study med                    |  |  |
| Randomization CRF                          |  |  |
| Follow-up visit                            |  |  |
| Follow-up source doc                       |  |  |
| Follow-up CRF                              |  |  |
| SAE/clinical event source                  |  |  |
| SAE sponsor worksheets                     |  |  |
| Queries                                    |  |  |
| <b>Monitor Visits</b>                      |  |  |
| Scheduling: PI, study manager, space       |  |  |
| Availability of charts                     |  |  |
| Availability of coordinator                |  |  |
| Policies relating to monitors              |  |  |
| Meeting with PI, research director         |  |  |
| <b>Required Reading</b>                    |  |  |
| Belmont report                             |  |  |
| Declaration of Helsinki                    |  |  |
| SOPs & policies                            |  |  |
| <b>Required Certifications / Tutorials</b> |  |  |
| HIPAA for Research Tutorial                |  |  |
| NIH Tutorial                               |  |  |
| Bloodborne Pathogens                       |  |  |
| Transportation of Dangerous Goods          |  |  |
| CTSC Clinical Research Training Program    |  |  |

I hereby acknowledge that I have been trained and understand the information outlined.

|                                      |                       |      |
|--------------------------------------|-----------------------|------|
|                                      |                       |      |
| Printed Name of Employee             | Signature of Employee | Date |
| Clinical Research Coordinator Mentor |                       | Date |