

COORDINATOR TRAINING CHECKLIST

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

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|------------------------------------------|------------------------------------------|----------------------------------------------------------------|
| Lab Preparation & Shipping | | |
| Tubes | | |
| Blood draw | | |
| Centrifuges | | |
| Safety precautions | | |
| Specimen handling | | |
| Shipping | | |
| Waste handling | | |
| | | |
| EKG | | |
| Lead placement & removal | | |
| Transmittal | | |
| Identifying problems | | |
| | | |
| Adverse Events | | |
| Definition | | |
| AE log | | |
| | | |
| SAEs | | |
| Definition and the difference | | |
| Reporting of SAEs | | |
| Sponsor | | |
| IRB | | |
| | | |
| | | |
| Concomitant meds & treatments | | |
| Definition | | |
| Start date & stop date | | |
| Dosing | | |
| Logs | | |
| | | |
| Study Management | | |
| Source documentation | | |
| CRF completion | | |
| Screen/Consent log | | |
| Enrollment log | | |
| Communication with physicians | | |
| Communication with other staff | | |
| Visit schedules & windows | | |
| Queries | | |
| | | |
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|--|-------------|-----------------|
| | Trained by: | Confirmation of |
|--|-------------|-----------------|

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| | (Trainer date & initials) | understanding (coordinator date & initials) |
|-------------------------------------------------------------------------|---------------------------|---------------------------------------------|
| Drug Accountability | | |
| Inventory | | |
| Dispensing logs | | |
| Documentation, labels, etc. | | |
| Patient compliance | | |
| Unblinding | | |
| Drug destruction policies | | |
| IVRS | | |
| | | |
| Regulatory Compliance | | |
| Initial study application to IRB | | |
| IND safety reports | | |
| IRB notification | | |
| Correspondence | | |
| | | |
| | | |
| Shipping | | |
| FedEx/UPS/World Courier | | |
| Mail | | |
| Certified mail – to lost to follow subjects | | |
| | | |
| Computer | | |
| HQ computer Systems | | |
| Dimensions -Organizational Policies- know how and where to access these | | |
| -HR Exempt, weather | | |
| | | |
| | | |
| | | |
| | | |
| Study Patient Evaluation | | |
| 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 | | |
| | | |
| Monitor Visits | | |

COORDINATOR TRAINING CHECKLIST

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|--------------------------------------------------------------------------------------------------------|--|--|
| Scheduling: PI, study manager, space | | |
| Availability of charts | | |
| Availability of coordinator | | |
| Policies relating to monitors | | |
| Meeting with PI | | |
| Tiger Text | | |
| Training | | |
| Basic Life Support | | |
| Study Specific training- List below | | |
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| Required Reading | | |
| Belmont report | | |
| Declaration of Helsinki | | |
| Research department SOPs | | |
| | | |
| Other Training | | |
| Clinical Research Introduction | | |
| Protection of human subjects | | |
| Shipping hazardous materials /Mayo online training | | |
| HIPAA | | |
| Webinars: | | |
| -Understanding Clinical Trials Protocols: Key Considerations for Effective Development and Feasibility | | |
| -IRB/IEC Responsibilities and Informed Consent | | |
| -Adverse Events and Safety | | |
| -Investigational Product | | |
| -Essential Documents | | |
| -Source Documents | | |

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

Printed Name of Employee

Signature of Employee

Date _____

Research Director Signature

Date _____