# ORIENTATION CHECKLIST – SKILLS aSSESSMENT

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|  | **Yes**Skill Level1 = low / none3 = moderate5 = advanced | **N/A** | **No**Develop a learning plan | **Learning Action Plan** | **Target Date** |
| **1. Process of Informed Consent:**A. PurposeB. Procedures C. BenefitsD. Risks and discomfortsE. Withdrawal/voluntaryF. ConfidentialityG. Assent of children (if applicable)H. Vulnerable subject (if applicable)I. Emergency (if applicable)J. Obtaining signaturesK. Impartial witness usedL. Legally acceptable representative**2. Vital Signs:**A. Blood Pressure (BP)B. Pulse C. RespirationsD. Temperature**3. Body Measurements:**A. WeightB. HeightC. Body Mass/Body Surface Area (BMI) | 1 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 5 | 🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏 | 🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏 |  |  |

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|  | **Yes**Skill Level1 = low / none3 = moderate5 = advanced | **N/A** | **No**Develop a learning plan | **Learning Action Plan** | **Target Date** |
| **4. Laboratory:**A. Correct TubesB. Venous Blood DrawC. Capillary Blood DrawD. Centrifuge Blood SamplesE. Safety PrecautionsF. Shipping Dangerous GoodsG. Universal PrecautionsH. Specimen Handling **5. EKG:**A. Placement of LeadsB. Computer Attachments C. Collection of ReportD. Removal of Leads**6. Adverse Events:**A. DefinitionsB. ParametersC. Reporting Unexpected AE’s**7.** **Serious Adverse Events:**A. DefinitionsB. ParametersC. Reporting SAE’sD. Informing Subjects (if applicable) | 1 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 5 | 🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏 | 🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏 |  |  |

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|  | **Yes**Skill Level1 = low / none3 = moderate5 = advanced | **N/A** | **No**Develop a learning plan | **Learning Action Plan** | **Target Date** |
| **8. Medications:**A. Dosage CalculationB. Dispensing C. Drug AccountabilityD. Drug InteractionsE. Drug OverdoseF. Drug AdministrationG. Drug StorageH. Drug Shipment – ReceivingI. Drug Shipment – Returning**9. Concomitant Medications:**A. DefinitionB. Start Date/Stop DateC. Dosing**10. Regulatory Documents:**A. Essential DocumentsB. Collection of DocumentsC. Organization of BinderD. Submission Process**11. REB Submission:**A. REB Guidelines B. Preparation of REB PackageC. Communication with REBD. Ongoing Reporting | 1 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 5 | 🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏 | 🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏 |  |  |

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|  | **Yes**Skill Level1 = low / none3 = moderate5 = advanced | **N/A** | **No**Develop a learning plan | **Learning Action Plan** | **Target Date** |
| **12. Informed Consent Form:**A. Essential ElementsB. DevelopmentC. Modifying Template**13. Patient Recruitment:**A. ScreeningB. RecruitmentC. Randomization**14. Clinical Trial Management:**A. Completion of Case Report FormsB. Assessment of ProtocolC. Amendments of ProtocolD. Amendments of Informed ConsentE. Subject Screening LogF. Subject Enrollment Log**15. Clinical Trial Administration:**A. Site Information Form B. Source DocumentationC. General Secretarial | 1 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 5 | 🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏 | 🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏 |  |  |

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|  | **Yes**Skill Level1 = low / none3 = moderate5 = advanced | **No**Develop a learning plan | **Learning Action Plan** | **Target Date** |
| **16. List of Other Skills Required for the Clinical Research Role:**1. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_2. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_3. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_4. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_5. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_6. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_7. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_8. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_9. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_10. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_11. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_12.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_13.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_14.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | 1 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 5 | 🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏 |  |  |

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| Signature of Person Completing Skills Assessment |  | Date of Completion |
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| Name (Print) |  | Title |