# ORIENTATION CHECKLIST – SKILLS aSSESSMENT

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|  | **Yes**  Skill Level  1 = low / none  3 = moderate  5 = advanced | **N/A** | **No**  Develop a learning plan | **Learning Action Plan** | **Target Date** |
| **1. Process of Informed Consent:**  A. Purpose  B. Procedures    C. Benefits  D. Risks and discomforts  E. Withdrawal/voluntary  F. Confidentiality  G. Assent of children (if applicable)  H. Vulnerable subject (if applicable)  I. Emergency (if applicable)  J. Obtaining signatures  K. Impartial witness used  L. Legally acceptable representative  **2. Vital Signs:**  A. Blood Pressure (BP)  B. Pulse    C. Respirations  D. Temperature  **3. Body Measurements:**  A. Weight  B. Height  C. Body Mass/Body Surface Area (BMI) | 1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5 | 🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏 | 🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏 |  |  |

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| **4. Laboratory:**  A. Correct Tubes  B. Venous Blood Draw  C. Capillary Blood Draw  D. Centrifuge Blood Samples  E. Safety Precautions  F. Shipping Dangerous Goods  G. Universal Precautions  H. Specimen Handling  **5. EKG:**  A. Placement of Leads  B. Computer Attachments    C. Collection of Report  D. Removal of Leads  **6. Adverse Events:**  A. Definitions  B. Parameters  C. Reporting Unexpected AE’s  **7.** **Serious Adverse Events:**  A. Definitions  B. Parameters  C. Reporting SAE’s  D. Informing Subjects (if applicable) | 1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5 | 🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏 | 🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏 |  |  |

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| **8. Medications:**  A. Dosage Calculation  B. Dispensing    C. Drug Accountability  D. Drug Interactions  E. Drug Overdose  F. Drug Administration  G. Drug Storage  H. Drug Shipment – Receiving  I. Drug Shipment – Returning  **9. Concomitant Medications:**  A. Definition  B. Start Date/Stop Date  C. Dosing  **10. Regulatory Documents:**  A. Essential Documents  B. Collection of Documents  C. Organization of Binder  D. Submission Process  **11. REB Submission:**  A. REB Guidelines    B. Preparation of REB Package  C. Communication with REB  D. Ongoing Reporting | 1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5 | 🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏 | 🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏 |  |  |

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| **12. Informed Consent Form:**  A. Essential Elements  B. Development  C. Modifying Template  **13. Patient Recruitment:**  A. Screening  B. Recruitment  C. Randomization  **14. Clinical Trial Management:**  A. Completion of Case Report Forms  B. Assessment of Protocol  C. Amendments of Protocol  D. Amendments of Informed Consent  E. Subject Screening Log  F. Subject Enrollment Log  **15. Clinical Trial Administration:**  A. Site Information Form    B. Source Documentation  C. General Secretarial | 1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5 | 🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏 | 🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏 |  |  |

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| **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 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5  1 2 3 4 5 | 🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏  🞏 |  |  |

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