

# Competency Assessment Form

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| **Employee name** |  | **Employee**  **Number** |  |
| **Clinical Trials Unit** |  | **Date commenced employment** |  |

The employee acknowledges they have completed all mandatory orientation as listed below;

* Read and understood all SWSLHD Standard Operating procedures
* Completed relevant orientation training and competency program
* Completed Good Clinical Practice Training

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| **Competency** | **Completed** | | **Date completed** |
| **Yes** | **No** |
| I have received the CTSU Clinical trials orientation manual and confirm that I read through the contents |  |  |  |
| 1. Feasibility, Site Initiation and Start up |  |  |  |
| 2. Ethics and Governance – An overview |  |  |  |
| 3. Recruitment, Documentation and Data Management |  |  |  |
| 4. Informed Consent |  |  |  |
| 5. Reporting Non Compliance and CAPA management |  |  |  |
| 6. Safety Assessment and reporting |  |  |  |
| 7. Monitoring Audits and Inspections |  |  |  |
| 8. Close Out and archiving |  |  |  |
| 9. Contracts and Budgets |  |  |  |
| 10. Veeva eISF – self directed |  |  |  |
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| Read and understood all SWSLHD Standard Operating procedures as provided on the CTSU website |  |  |  |
| Completed Good Clinical Practice Training within 1 month of commencing employment |  |  |  |
| **Additional Training as required** |  |  |  |
| e.g. IATA Dangerous goods training |  |  |  |
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Comments

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| **Signature of Employee** |  |
| **Signature of Manager** |  |
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