# EMPLOYEE Assessment - Regulations and Guidelines

(To be completed at time of hire and then annually)

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| **Regulations and Guidelines**  **Knowledge Assessment Questions** | **Yes**  Indicate Level\* | No  Develop a learning plan | Learning Action Plan | **Target Date** |
| 1. General regulation knowledge needs:   A. ICH GCP Guidelines  B. ICH GCP Essential Documents  C. Health Canada Food and Drug Act Regulations  D. FDA Regulations  E. Tri-Council Policy Statement  F. PIPEDA | 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. Has attended a GCP course | 🞏 | 🞏 |  |  |
| 1. Has read the following:   A. ICH GCP Guidelines  B. ICH GCP Essential Documents  C. Health Canada Food and Drug Act Regulations  D. FDA Regulations  E. Tri-Council Policy Statement  F. PIDEDA | 🞏  🞏  🞏  🞏  🞏  🞏 | 🞏  🞏  🞏  🞏  🞏  🞏 |  | \_\_\_\_\_\_\_  \_\_\_\_\_\_\_  \_\_\_\_\_\_\_  \_\_\_\_\_\_\_  \_\_\_\_\_\_\_  \_\_\_\_\_\_\_ |
| 1. Has taken a course in:   A. Health Canada Food and Drug Act Regulations  B. Health Canada Inspections  C. FDA Regulations  D. FDA Audits  E. Tri-Council Policy Statement  F. PIPEDA | 🞏  🞏  🞏  🞏  🞏  🞏 | 🞏  🞏  🞏  🞏  🞏  🞏 |  | \_\_\_\_\_\_\_  \_\_\_\_\_\_\_  \_\_\_\_\_\_\_  \_\_\_\_\_\_\_  \_\_\_\_\_\_\_  \_\_\_\_\_\_\_ |
| 1. Has completed NIH online course “Human Participant Protections: Education for Research Teams” | 🞏 | 🞏 |  |  |

\*Knowledge Level: 1 = minimal / none; 3 = adequate; 5 = well-versed

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