# 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\* | NoDevelop a learning plan | Learning Action Plan | **Target Date** |
| 1. General regulation knowledge needs:

A. ICH GCP GuidelinesB. ICH GCP Essential DocumentsC. Health Canada Food and Drug Act RegulationsD. FDA RegulationsE. Tri-Council Policy StatementF. PIPEDA | 1 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 51 2 3 4 5 | 🞏🞏🞏🞏🞏🞏 |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1. Has attended a GCP course
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| 1. Has read the following:

A. ICH GCP GuidelinesB. ICH GCP Essential DocumentsC. Health Canada Food and Drug Act RegulationsD. FDA RegulationsE. Tri-Council Policy StatementF. PIDEDA | 🞏🞏🞏🞏🞏🞏 | 🞏🞏🞏🞏🞏🞏 |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1. Has taken a course in:

A. Health Canada Food and Drug Act RegulationsB. Health Canada InspectionsC. FDA RegulationsD. FDA AuditsE. Tri-Council Policy StatementF. PIPEDA | 🞏🞏🞏🞏🞏🞏 | 🞏🞏🞏🞏🞏🞏 |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1. Has completed NIH online course “Human Participant Protections: Education for Research Teams”
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\*Knowledge Level: 1 = minimal / none; 3 = adequate; 5 = well-versed

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