**For-Cause Clinical Audit Follow-Up Report**

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| Principal Investigator | |
| Name |  |
| Department |  |
| Address |  |
| Study Title |  |
| Audit Date |  |

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| --- | --- |
| Audit Team | |
| Name(s) | Radwa Aly, Sarah Ford-Trowell |
| Department | Office of Clinical Research and Division of Regulatory and Compliance |
| Address | George Washington School of Medicine and Health Sciences and Medical Faculty Associates  2150 Pennsylvania Ave NW  Washington DC / USA 20052 |

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| **1.0 Introduction** |

This Follow-Up Report includes the main findings, observations, and corrective actions for you and your research team. We note that Follow-up Report will be provided to the cognizant Institutional Review Board, which may make additional findings, require additional corrective actions and/or impose sanctions.

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| **2.0 Background** |

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| **3.0 Aim** |

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| **4.0 Objectives** |

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| **5.0 Standards** |

The regulatory standards guiding the audit are:

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| Good Clinical Practice (GCP) | No exceptions |

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| **6.0 Data Sources and Methodology** |

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| **7.0 Findings and Corrective Action Plan** |

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| For-Cause Audit- NCR191914-01 | | |
| Finding | Category (Major or Minor) | Corrective Action |
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| **8.0 Conclusion** |

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| **9.0 Signatures** |

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| Sarah Ford-Trowell, Sr Manager Regulatory and Compliance | Date |
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|  |  |
| Radwa Aly, Executive Director Clinical Research Operations | Date |