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| 11. APPENDIX 1[**FRM 75**](https://rderesearch.co.uk/templates-forms/) **Corrective Action and Preventive Action (CAPA) Plan**

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| **Study (or non-related study) Title** |  |
| **Responsible person (e.g. CI, Local PI)** |  |

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| --- | --- | --- |
| **Details of deficiency or non-compliance e.g.** What happened and what was observed? What should have happened? | **Date of deficiency or non-compliance:** | **CAPA Reference No.** |
| *
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*
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| **CAPA Owner** | **CAPA Initiator**  |

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|  | **Action(s)** | **Corrective or Preventative?** | **Due Date** | **Responsible person** | **Notes** | **Date action complete** |
| 1 |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |
| 3 |  |  |  |  |  |  |
| 4 |  |  |  |  |  |  |
| 5 |  |  |  |  |  |  |

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| **Effectiveness of Actions** |
| **Evidence Actions have resolved the deficiency/non-compliance(s):***
*
*

**Deficiency/non-compliance resolved? Yes No** **If no, detail next steps:**  |

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| **Confirmation of CAPA Closure** |
| **Date CAPA closed** | **Confirmed by** | **Role** | **Signature** |
|  |  |  |  |
| **Confirmation of No Reoccurrence of CAPA** |
| **Date CAPA closed** | **Confirmed by** | **Role** | **Signature** |
|  |  |  |  |

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| **Quality Assurance Confirmation of CAPA closure** |
| **Name:****Role:****Signature: Date:** |