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| --- | --- | --- | --- | --- | --- |
|  | | **Temp Excursion/Damage ID #** | | |  |
| *ID # to be assigned by RECOVERY team* | | | | | |
| **Section 1: Site to complete the following information** | | | | | |
| Study/protocol #: RECOVERY | | | | | |
| PI Name: | | | Date: | | |
| Reporter Name: | | | Reporter email: | | |
| **Temperature Excursion:** ☐ **N/A** | | | Date excursion identified: ☐ **N/A** | | |
| Date started: | | | Time started: | | |
| Date ended: | | | Time ended: | | |
| Minimum temperature: | | | Maximum temperature: | | |
| Date damage Identified and description of damage (if possible, provide pictures): ☐ **N/A** | | | | | |
| **Product Description:** | **Packaging Lot#:** | | **Quantity**  (# of units) | **Unique Product ID #**  (e.g., Med ID#, Kit ID# or Vial ID #) | |
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|  |  | |  |  | |
| Further details on the temperature excursion/damage: | | | | | |
| **Immediate Actions:** | | | | | |
| Products placed in Quarantine at Event Location: ☐ Yes ☐ No  Has any affected product been dosed to patients: ☐ Yes ☐ No  Temperature report attached: ☐ Yes ☐ No | | | | | |
| Email completed form, pictures and/or temperature data to [recoverytrial@ndph.ox.ac.uk](mailto:recoverytrial@ndph.ox.ac.uk) | | | | | |

|  |  |
| --- | --- |
| **Section 2: RECOVEY Team to complete Investigation/IMP Disposition** | |
| Summary of quality assessment: | |
| IP Disposition: | * Suitable for clinical use ☐ Not suitable for clinical use (Return or Destroy)\* * Refer to VIR for further assessment   *\*Please follow process per the Pharmacy Manual* |

*Completed form to be filed both at CCO and site.*

*Site copy to be filed within pharmacy file, with a file note in the ISF to indicate this location.*