|  |  |  |
| --- | --- | --- |
|  | **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 ☐ NoTemperature report attached: ☐ Yes ☐ No |
| Email completed form, pictures and/or temperature data to 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.*