1. **Purpose**

To outline the process by which the Office of Sponsor and Regulatory Oversight (OSRO) will document an emergency transfer of study subject clinical care from the National Institutes of Health’s (NIH) National Cancer Institute’s Center for Cancer Research (NCI CCR) to a qualified non-NIH medical facility.

2. **Scope**

2.1. This SOP is applicable only when NIH NCI CCR operations are disrupted due to circumstances outside the control of NIH, e.g. natural and manmade disasters, local and national emergencies.

2.2. Controlled clinical trials under NIH NCI CCR-held INDs may use this procedure.

2.3. **Limitation**

2.3.1. The use of this process will reclassify subject research data; consequently, the data will no longer qualify to support the clinical trial.

3. **Responsibilities**

3.1. The OSRO Director approves the emergency use of a qualified non-NIH medical facility.

3.2. OSRO Regulatory communicates the emergency use to the Food and Drug Administration (FDA).

4. **References**

4.1. 204 Investigators’ Responsibility Policy

5. **Definitions**

Refer to the OSRO Lexicon.

6. **Procedure**

6.1. When an emergency has occurred or is pending, OSRO will send the CCR Principal Investigators (PIs) a copy of F01-204-S01 Contingency Plan Communication to NIH Principal Investigators.

6.1.1. F01-204-S01 Contingency Plan Communication to NIH Principal Investigators instructs PIs of requisite documentation and actions required by OSRO in order to obtain OSRO approval for transferring protocol-driven procedures to a non-NIH medical facility.

6.2. Transfer of the subject to a non-NIH medical facility during an emergency is done for the safety and welfare of the subject.

6.3. OSRO must receive the following documents from the CCR PI:

6.3.1. Completed F02-204-S01 Plan for Use of Qualified Non-NIH Facility.

6.3.1.1. This form is completed by the CCR PI.

6.3.2. Completed F03-204-S01 Non-NIH Facility Information.
6.3.2.1. Section 1 of the form is completed by the CCR PI; Section 2 is completed by a physician at the non-NIH facility.

6.3.3. Justification for why a study subject must continue to receive the investigational product.

6.3.4. Copies of the CCR PI / non-NIH PI approved plans for how serious adverse events (SAEs) and other safety events will be reported, communication methods and CCR PI remote oversight.

6.3.5. As the non-NIH facility will not be engaged in research, if the CCR PI determines that extraction of data from the non-NIH facility medical records is appropriate, the plan for data collection/extraction should be provided as well.

6.3.6. Agreement between the pharmaceutical collaborator and the NIH Clinical Center (CC) pharmacy is in place.

6.3.6.1. If this not obtained by the CCR PI, then OSRO will ensure that an agreement exists.

6.3.7. NIH Institutional Review Board (IRB) agreement of the plan.

6.3.8. If the investigational product is to be shipped to a non-NIH medical facility, then the following documents are required:

6.3.8.1. Revised Form FDA 1572 listing the non-NIH medical facility.

6.3.8.2. Product shipment log, including temperature monitoring during transit.

6.3.8.3. Drug Accountability records from the non-NIH medical facility.

6.4. The FDA will be notified prior to implementation.

6.5. This document shall be reviewed periodically and updated as necessary.

7. Associated Documents

7.1. F01-204-S01 Contingency Plan Communication to NIH Principal Investigators

7.2. F02-204-S01 Plan for Use of Qualified Non-NIH Facility

7.3. F03-204-S01 Non-NIH Facility Information

8. Change Summary

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<tr>
<th>Revision Number</th>
<th>Effective Date</th>
<th>Description of Change</th>
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<td>1</td>
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<td>New Document</td>
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