1. Purpose

To ensure that each National Cancer Center (NCI) Center for Cancer Research (CCR) Investigational New Drug Application (IND) study investigational product (IP) has a corresponding Unique Ingredient Identifier (UNII) for accurate and comprehensive IP-specific tracking.

2. Scope

2.1. Queries to the Food and Drug Administration’s Substance Registration System (FDA-SRS) for determining UNII assignment, application for a UNII and tracking of IP-UNII cross references are in scope.

2.2. Limitations

2.2.1. This procedure applies to clinical studies conducted under CCR-held INDs under Office of Sponsor and Regulatory Oversight (OSRO) oversight.

3. Responsibilities

3.1. OSRO Pharmaceutical Management is responsible for tracking UNII assignments to IPs.

4. References

4.1. FDA’s Global Substance Registration System

5. Definitions

Refer to the OSRO Lexicon.

6. Procedure

6.1. FDA Substance Registration System (FDA-SRS) UNII verification and tracking

6.1.1. OSRO Pharmaceutical Management will query the FDA-SRS (https://fdasis.nlm.nih.gov/srs/) to determine if an assigned UNII exists.

6.1.2. If no UNII is assigned in the FDA-SRS and NCI is the manufacturer of the IP:

6.1.2.1. Applicable information for a request will be compiled by OSRO Pharmaceutical Management from the IND/protocol status spreadsheet. OSRO Pharmaceutical Management will submit a UNII request via email to FDA-SRS@fda.hhs.gov.

6.1.2.1.1. If denied/rejected or if FDA-SRS provides an existing UNII, the FDA-SRS response will be filed in the OSRO IP file.

6.1.2.1.2. If approved, documentation of the assigned UNII will be routed to the OSRO Director and OSRO Regulatory.
6.1.3. If no UNII is assigned in the FDA-SRS and NCI is not the manufacturer of the IP:

6.1.3.1. OSRO Pharmaceutical Management will submit a UNII query via email to FDA-SRS@fda.hhs.gov to determine if a UNII exists but has not been included in the database. The query will be specific in nature and will not serve as a request for the creation of a UNII.

6.1.3.1.1. If query is denied/rejected or if FDA-SRS provides an existing UNII, the FDA-SRS response will be filed in the OSRO IP file.

6.1.3.1.2. If an existing UNII is provided, documentation of the assigned UNII will be routed to the OSRO Director and OSRO Regulatory.

6.1.3.1.3. If no UNII is provided, either due to nonexistence or privacy due to proprietary information, the manufacturer will be contacted by OSRO Pharmaceutical Management to request an update on the UNII number status.

6.1.4. If or when there is an existing UNII in the FDA-SRS:

6.1.4.1. Within five (5) business days of receipt, OSRO Pharmaceutical Management will assign the UNII to IP in a key (with name and UNII).

6.1.4.2. An email notification with the UNII and IP name will be sent to OSRO Regulatory and OSRO Quality.

6.1.4.3. As warranted, the existing OSRO databases and the eTMF will be updated by the respective OSRO task area responsible for information maintenance.

6.2. Before the UNII is assigned or known, the IP medication name will be used to reference the IP.

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

7. Associated Documents

7.1. OSRO Regulatory’s IND/protocol status Excel spreadsheet

7.2. OSRO Pharmaceutical Management’s IP/UNII Log

8. Change Summary

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<th>Revision Number</th>
<th>Effective Date</th>
<th>Description of Change</th>
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<tr>
<td>1</td>
<td>28JUL2020</td>
<td>New Document</td>
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