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 Global Substance Registration System (FDA-SRS) for determining UNII assignment and application for a UNII are in scope.

2.2. Limitation

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 manages the tracking of UNII assignments to IPs.

3.1.1. The OSRO Sponsor and Regulatory Oversight Support (SROS) Contractor assists OSRO Pharmaceutical Management as needed.

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 or its SROS Contractor designee will query the FDA-SRS (https://precision.fda.gov/uniisearch) 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 from the IND/protocol status spreadsheet. A UNII request will be submitted 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 electronic Trial Master File (eTMF).

6.1.2.1.2. If approved, documentation of the assigned UNII will be routed to the OSRO Director and OSRO Regulatory and archived in the eTMF.

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

6.1.3.2. OSRO Pharmaceutical Management or its SROS Contractor designee 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.

6.1.3.2.1. If the query is denied/rejected or if FDA-SRS provides an existing UNII, the FDA-SRS response will be filed in the eTMF.

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

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

6.1.4.1. An email notification with the UNII and IP name will be sent to OSRO Regulatory and the OSRO Director and archived in the eTMF.

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

7. Associated Documents

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

8. Change Summary

Revision Number	Effective Date	Description of Change
1	28JUL2020	New Document
2	19NOV2021	Step 3.1.1 – step added Steps 6.1.1, 6.1.3.1 and 6.1.4.1 – added the phrase "or its SROS Contractor designee" Step 6.1.3.1 – moved from end of section 6.1.3 to beginning Step 7.2 – corrected document notation Minor changes to language and formatting.
3	10MAY2023	Updated grammar and process as needed Clarified archival location as the eTMF Step 7.2 – removed