## 1. Purpose

To provide the process by which the Office of Sponsor and Regulatory Oversight (OSRO) documents a change in a clinical study status under specific circumstances.

## 2. Scope

2.1. This SOP applies to studies conducted under a Center for Cancer Research (CCR)-held Investigational New Drug application (IND), Investigational Device Exemption (IDE) or Non-Significant Risk Device (NSR) under OSRO oversight.

2.2. Study statuses identified as one of the following are within scope.

- Development terminated
- Enrollment suspended
- Enrollment and treatment suspended
- Recruiting/Enrollment (if study was previously suspended)
- Terminated
- Withdrawn

## 3. Responsibilities

3.1. OSRO Operations receives notifications of study status changes and requests SROS to update protocol-specific information in the electronic Trial Master File (eTMF).

3.2. OSRO Functional Groups relay notifications of study status changes to OSRO Operations.

3.3. OSRO Sponsor and Regulatory Oversight Support (SROS) contractor staff assist OSRO Functional Groups as needed.

## 4. References

4.1. 205 Clinical Site Monitoring Policy

## 5. Definitions

Refer to the OSRO Lexicon.

## 6. Procedure

6.1. OSRO staff who receive a notification to change the status of a clinical study under OSRO oversight to one of the statuses identified in Table 1 shall forward the notification to OSRO Monitoring (NCIOSROMonitoring@mail.nih.gov) within two (2) business days of receipt.

6.2. OSRO Operations prepares F01-205-S05 Request to Update Study Status in the eTMF within two (2) business days of receiving the written notification.

6.2.1. The protocol number, the IND number, the updated study status and the new status date are required.

Table 1.

| Status | Definition | Requirement for Status Assignment |
|---|---|---|
| **Development terminated** | Protocol development has been terminated | The PI or OSRO has decided to terminate protocol development. |
| **Enrollment suspended** | The study is active, but enrollment is temporarily paused. Currently enrolled participants continue to receive treatment | The PI and OSRO have decided to suspend enrollment (e.g., due to safety concerns, insufficient IP, funding, etc.). This excludes enrollment suspensions due to FDA-mandated clinical holds. |
| **Enrollment and treatment suspended** | The study is active, but enrollment and treatment are temporarily paused | The PI and OSRO have decided to suspend enrollment and treatment (e.g., due to safety concerns, insufficient IP, funding, etc.). This excludes enrollment suspensions due to FDA-mandated clinical holds. |
| **Recruiting/Enrollment** | The study has begun recruiting and/or enrolling participants following a suspension. | At least one site has started recruiting participants following a suspension. |
| **Terminated** | The study has stopped early and will not start again. Participants are no longer being examined or treated. | All participants are off-study; the enrollment target has not been reached yet, and the PI and OSRO have decided that the study will not be resumed. |
| **Withdrawn** | The study stopped early, before enrolling its first participant. | No participants have been enrolled and the PI and OSRO have decided to terminate the study. |

6.3. OSRO Operations sends the completed F01-205-S05 to SROS TMF (SROSTMF@tech-res.com) within two (2) business days of receiving the written notification.

6.3.1. The email should be sent from OSRO Monitoring (NCIOSROMonitoring@mail.nih.gov).

6.3.2. A carbon copy should be sent to the OSRO Director and the leads of OSRO Safety, OSRO Regulatory and OSRO Pharmaceutical Management.

6.3.3. For protocols changing to the status "Development terminated," SROS Study Information Office (SROSSIO@tech-res.com) and SROS Protocol Review (SROSProtocolReview@tech-res.com) should be copied.

6.4. OSRO Operations files the completed F01-205-S05 on the CCROSRO-CSM SharePoint.

6.5. SROS staff is responsible for updating the eTMF.

6.5.1. The study status and study status date metadata should be updated.

6.5.2. The submitted F01-205-S05 Request to Update Protocol Status in the eTMF should be filed under the protocol-specific artifact.

## 7. Associated Documents

7.1. F01-205-S05 Request to Update Study Status in the eTMF

## 8. Change Summary

| Revision Number | Effective Date | Description of Change |
|---|---|---|
| 1 | 23JUN2023 | New Document |